

**PRESCRIPTION DRUG ABUSE AND DIVERSION: THE
ROLE OF PRESCRIPTION DRUG MONITORING
PROGRAMS**

HEARING
OF THE
**COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS**
UNITED STATES SENATE
ONE HUNDRED EIGHTH CONGRESS
SECOND SESSION
ON

EXAMINING DRUG ABUSE PREVENTION ISSUES, FOCUSING ON THE
ROLE OF PRESCRIPTION DRUG MONITORING PROGRAMS, AND FED-
ERAL PRIVACY STANDARDS FOR PMPS

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THURSDAY, SEPTEMBER 23, 2004

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The committee met, pursuant to notice, at 2:08 p.m., in room SD-430, Dirksen Senate Office Building, Hon. Jeff Sessions, presiding.

Present: Senator Sessions.

OPENING STATEMENT OF SENATOR SESSIONS

Senator SESSIONS. Good afternoon. I am Senator Jeff Sessions, and I appreciate your attendance at a hearing today that I think will be interesting and deals with a very significant and important subject that may not solve all the problems we have in the world, but it deals with a very significant, discrete problem that is growing in America today. I want to thank Senator Judd Gregg, chairman of our Health, Education, Labor, and Pensions Committee, for allowing and encouraging us to have this hearing. And we have a good panel, and we will be discussing an important issue.

Over the past 10 years, the abuse and diversion of prescription drugs has grown from a regional crisis to a national epidemic. The Substance Abuse and Mental Health Services Administration recently released the studies of the 2003 National Survey on Drug Use and Health. Newspapers across the country reported the data that suggested that while the use of illicit drugs, such as cocaine, remained steady or even declined, the figure on the nonmedical use of prescription medications had a different story.

Prescription drugs now rank second only to marijuana in the incidence of abuse. In a 1-year period, the number of nonmedical users of pain relievers increased to a total of 31.2 million American adolescents and adults who have abused these medications at least one time in their lifetime. The number of first-time abusers, those who have abused prescription drugs for the first time, has increased 336 percent since 1990. And make no mistake, prescription drug addiction is a powerful addiction.

While press coverage has frequently focused on the abuse and diversion of OxyContin and other narcotic pain relievers, it is clear that this problem extends to several classes of commonly prescribed drugs, including tranquilizers and stimulants. In fact, the 2003 Na-

tional Survey data reflected an ever sharper increase in the non-medical use of tranquilizers.

All in all, it is estimated that over 6 million Americans are current abusers of prescription drugs that fall within these classes. The black market in diverted prescription drugs is now a multibillion-dollar industry. I remember as a Federal prosecutor that drugs like Dilaudid were regularly sold on the streets of our communities for \$60 to \$80 a pill, and it results in a powerful addiction.

These numbers, tens of millions, frequently obscure the human tragedy of drug abuse and dependence. Each of us has heard the news stories of famous persons who have developed prescription drug abuse problems, and for many it has hit close to our own homes. Frequently, these stories involved a legitimate first prescription that evolves into an addiction and familiar pattern of drug-seeking behavior that takes addicts from doctor to doctor to get their kicks.

To their credit, doctors do not want to be a part of this cycle. In fact, physicians have been the leading advocates for effective programs to combat prescription drug abuse and diversion. I remember in around 1990 I chaired a committee in Alabama on law enforcement issues, and we spent a lot of time on this very issue. We were amazed how much abuse of prescription drugs there was in the city of Mobile, and a number of steps were taken that improved that. We even discussed legislation that would create a system somewhat like this for the State of Alabama.

This epidemic has driven, though, additional societal costs. The addicted fall from the productive ranks of society into unemployment, disability, hospitalization, and, too frequently, crime and incarceration. Their families and communities suffer along with them. Taxpayers bear the expense of purchasing abused or illegally diverted drugs through public programs and subsequently treating the medical consequences of misuse and addiction. Law enforcement agencies, particularly in rural areas, are stretched beyond their limits as the scourge sweeps through depressed and disadvantaged communities particularly.

The physician-patient relationship has suffered as well. The growing addiction problem and the black market that feeds it has created an atmosphere in which physicians fear that prescribing certain high-risk medications could lead to civil liability or professional discipline. As a result, the problem has created yet another class of victims: patients who might find it more difficult to obtain timely, effective treatment for pain and other legitimate medical needs.

Clearly, the solution depends on early identification and intervention of those who may be becoming addicted to illicit drugs. If you can intervene early before a person has sustained a serious addiction, that is the best time to do it.

The purpose of today's hearing is to attempt to develop some sense of the scope and nature of this problem and then to look beyond the tragic losses and tremendous costs to potential solutions. So I am particularly interested in an approach that has been adopted by a growing number of States and has shown promising results: the prescription drug monitoring program. At the present time, 19 States have operating prescription drug monitoring pro-

grams. These monitoring programs have been used by health care providers to better deliver appropriate, effective treatment of pain and other conditions that require the use of scheduled drugs and to identify and, if appropriate, refer for treatment patients whose prescription history suggests that they are at risk for addiction.

I am interested also in the extent to which such systems could enhance the ability of law enforcement to better direct its resources to reduce this problem and to reduce the investigation times. Additionally, at a time when no discussion of health care should avoid the topic of cost, Federal, State, and private payers frequently are the ones who shoulder the substantial burden of purchasing diverted drugs as well as treating the medical sequelae of abuse. Finding a cost-efficient tool to effectively reduce the incidence of diversion and abuse could be expected to provide substantial savings, particularly for many States' financially strapped Medicare programs.

It appears the States that have instituted prescription drug monitoring programs have realized substantial benefits. A 2002 GAO study of these programs concluded that prescription monitoring programs appear to have reduced illegal drug diversion. However, several important issues were raised, including the fact that while States with monitoring programs saw a reduction in drug diversion activity, their neighboring States without programs tended to experience a corresponding rise, and addicts and black marketeers shifted their efforts across State borders.

I am pleased that after several years of effort and with my full support, my own State of Alabama is moving toward instituting a prescription drug monitoring program. Of course, Alabama's program will likely affect our neighbors in Mississippi and Tennessee and Georgia and Florida. Certainly coordination among States' programs is a matter we must discuss. In keeping with the broadly shared goal of improving health information technology capabilities throughout the health care system—and we need to do more of that—testimony will also focus on current legal and technical barriers to making a relevant patient medication history available to appropriate parties and for appropriate purposes across State lines.

Despite sharing many common elements, these programs do differ, and any Federal effort to improve on or expand prescription drug monitoring must take these differences into account.

We will include in the record at this point the prepared statement of Senator Kennedy.

[The prepared statement of Senator Kennedy follows:]

PREPARED STATEMENT OF SENATOR EDWARD M. KENNEDY

I commend my colleague, Senator Sessions, for holding today's hearing on the growing national concern over prescription drug abuse. Over 6 million Americans use prescription medications for non-medical purposes. Since 1992, the number of young adults who abuse prescription pain relievers and other potentially addictive drugs has more than tripled, and prescription drug abuse among youths aged 12 to 17 has increased ten fold.

State programs to monitor the prescribing of potentially addictive medications can help curb this abuse. Currently, 19 States have monitoring programs in place, including Massachusetts. The infor-

mation can be used to identify physicians and patients who encourage the non-medical use of prescription drugs and can also be used to reduce the diversion of prescription drugs for illegal purposes.

Any such program, however, must include strong safeguards for medical privacy, and make certain that the database cannot be used to bring improper pressure on physicians to avoid prescribing essential medication for patients in need. The proper treatment of patients in pain, for example, is an enormous medical challenge, but this essential work will be more difficult if patients fear that the privacy of their prescription histories will not be protected, or if physicians begin to look over their shoulders every time they prescribe needed pain medication.

Congressman Whitfield and Congressman Pallone have introduced legislation to establish a national electronic database to monitor these prescriptions, and I understand that Senator Sessions may introduce similar legislation in the Senate. We all share the goal of striking the right balance between the interests of patients, physicians, and law enforcement, and I'm confident we can work together to enact legislation that achieves this balance.

The current House legislation, however, grants law enforcement officials access too easily to the information in the database. Under the House bill, if law enforcement officials feel the information will strengthen an investigation, they are granted access to it, without obtaining a court order, and without requiring a review of the validity of the requests before granting access to sensitive medical information.

Massachusetts' State monitoring program includes important safeguards against improper use of information in the database. It also protects against intrusive use of the database by law enforcement agencies, and it includes a peer review group of health professionals to review data collected by the program for signs of abuse or diversion. If the expert group identifies data suggesting misuse, the Public Health Commissioner is notified, and the Commissioner and the review group decide whether to handle the situation internally or notify law enforcement.

If a law enforcement authority requests data on a specific physician or patient, the peer review group analyzes the data requested. If the data suggests abuse or diversion, they fulfill the request. If the evidence is inadequate, the review group will decline to release sensitive medical information.

The peer review group is thus a protector and gatekeeper for the data in the State monitoring program. Massachusetts has successfully implemented its monitoring system, and has taken steps to protect the privacy of medical records and avoid undermining the trust between doctor and patient.

I commend Senator Sessions for bringing the attention of the committee to this important issue, and for highlighting the benefits of a national electronic database to monitor misuse. I look forward to working with our colleagues on the committee to see that the legislation protects patient privacy and prevents data from being abused.

I commend our witnesses for their testimony today, and I look forward to their recommendations.

Senator SESSIONS. We have a very distinguished group of witnesses before the committee today. I think Congressman Whitfield is not with us at this point, not yet, and we expect him to join us in a little bit. But we will start with our larger panel first.

I also see my former colleague, Tim Hutchinson. Tim, thank you for your leadership on this issue and bringing to my attention the importance of this issue.

This very distinguished group of witnesses before the committee today should be able to shed some important light on these matters. I look forward to the opportunity that this will provide Members of Congress to develop a better understanding of this problem and to carefully consider how to provide the most useful and appropriate Federal response.

Our first panel will consist of four additional witnesses: Dr. James Holsinger, the Secretary of the Kentucky Cabinet for Health and Family Services—Jim, you can step on up, and I believe your name tag is there—the agency in Kentucky that administers the prescription drug monitoring program. Dr. Holsinger can provide important details on the operation and impact of the KASPER program. He also is a writer and author, having written an exceptionally fine book on the Methodist Church that is read throughout the denomination, and I can say with certainty it has been a positive influence for the denomination.

Dr. Kenneth Varley is the president of the Alabama Society of Interventional Pain Physicians and is a practicing pain specialist in Birmingham, Alabama.

Sherry Green is the executive director of the National Alliance on Model State Drug Laws, an organization that has provided important legal and technical guidance for States that have elected to implement monitoring programs and other drug laws that you help them with.

Finally, Joy Pritts is currently an assistant research professor at Georgetown University's Health Policy Institute and an expert who has published extensively and testified before Congress on medical privacy matters. Thank you, Ms. Pritts. We are going to hear from you on the privacy question.

So I look forward to hearing from you, and, Dr. Holsinger, if you would begin, we would be glad to hear your testimony. And our time limit will be about 5 minutes. The light will turn red up here, I believe, and you do not sink into the ocean if you go beyond, but, Dr. Holsinger, we are delighted to have you with us.

STATEMENTS OF HOLSINGER, JAMES W., JR., M.D., SECRETARY, KENTUCKY CABINET FOR HEALTH AND FAMILY SERVICES; SHERRY GREEN, EXECUTIVE DIRECTOR, NATIONAL ALLIANCE FOR MODEL STATE DRUG LAWS, ALEXANDRIA, VA; KENNETH G. VARLEY, M.D., PRESIDENT AND EXECUTIVE DIRECTOR, ALABAMA SOCIETY OF INTERVENTIONAL PAIN PHYSICIANS, AND BOARD MEMBER, AMERICAN SOCIETY OF INTERVENTIONAL PAIN PHYSICIANS; AND JOY L. PRITTS, ASSISTANT RESEARCH PROFESSOR, HEALTH POLICY INSTITUTE, GEORGETOWN UNIVERSITY

Dr. HOLSINGER. Senator Sessions, it is a real pleasure to be here with you today. I am here to discuss briefly Kentucky's implemen-

tation of a prescription drug monitoring program, the status of the current system enhancements, and the goals of the Commonwealth of Kentucky in detecting and preventing prescription drug abuse and diversion.

Before I begin, I would certainly like to thank and recognize Congressman Ed Whitfield who is passionate about wanting us to work toward reducing the abuse of prescription drugs in the Commonwealth and beyond, and also Congressman Hal Rogers, the Dean of Kentucky's congressional delegation, for all of his hard work to reduce the abuse of prescription drugs.

Senator SESSIONS. Dr. Holsinger, I would say that I understand the House is in a series of votes. Congressman Whitfield came by and talked to me yesterday. I am sure he will be here when he can break free.

Dr. HOLSINGER. There is no question that prescription drug abuse and diversion is a public health crisis of significant magnitude. Accordingly, failing to combat this issue with great vigor on multiple fronts and in a highly coordinated fashion will undoubtedly lead to dire health and safety consequences nationwide.

Prescription drug monitoring programs are designed to help prevent and detect the diversion and abuse of pharmaceutical controlled substances, particularly at the retail level. States that have implemented prescription monitoring programs have the capability to collect and analyze prescription data much more efficiently than States without such programs, where the collection of prescription information requires the manual review of pharmacy files, a time-consuming and invasive process.

The purpose of PMPs is to enhance the ability of health care professionals, as well as regulatory and law enforcement agencies, to collect and analyze controlled substance prescription data. This is accomplished by building a data collection and analysis system at the State level, enhancing programs' ability to analyze and use collected data, and facilitating the exchange of collected prescription data among States. The increased efficiency of prescription monitoring programs allows for the early detection of abuse trends and possible sources of diversion. In your packet is a chart that depicts the KASPER process, as well as some rather impressive statistical information generated from the program.

I think one of the most impressive things that we deal with is the fact that of the individuals and organizations that enter the system, 85 percent of those are physicians, indicating a high degree of acceptance on their part.

Kentucky's prescription drug monitoring program was established during the Kentucky General Assembly's 1998 legislative session, and the program became operational in 1999.

It is commonly referred to as "KASPER," which is the acronym for the Kentucky All Schedule Prescription Electronic Reporting system. This system automated the processing of data to support the tracking and sharing of information in accordance with existing statutes governing controlled substance prescriptions.

KASPER was created with two main goals in mind: first, to be a source of information for physicians and pharmacists; and, second, to be an investigative tool for law enforcement. KASPER is

the instrument that enables this information to be collected, analyzed, and shared rapidly.

Data gets into the relational database as dispensers transmit prescription data to our data collection agent by modem, diskette, or tape. The data collection agent then verifies, compiles and sends the data to the Drug Enforcement and Professional Practices Branch to be loaded into the KASPER server.

Very high security procedures protect access to the data with only branch personnel having access to information within the KASPER database. Reports requested by authorized individuals also undergo a high level of scrutiny. Release of data to anyone not authorized by Kentucky's statute is a Class D felony.

Currently, there are approximately 30 States with some form of a PMP in operation although only Kentucky, Michigan, and Nevada have electronic systems requiring the collection of data on all scheduled drugs. In Kentucky, the KASPER program is administered by the Cabinet for Health and Family Services' Office of Inspector General. Controlled substance prescription reports, KASPER reports, are available to physicians, in the treatment of patients; pharmacists, in the treatment of patients; law enforcement, in conjunction with a bona fide investigation; professional licensure boards, in investigation of their members; Medicaid departments, for prevention of fraud and abuse; and by grand jury subpoena and court orders.

Many of the clinicians in the State were skeptical when KASPER was initiated. They felt the scrutiny implied by a monitoring program would interfere with their practice. In actuality, they have found that by utilizing the program to monitor their patients chronically utilizing controlled substances, they have documentation to prove they are treating these patients judiciously. Indeed, as a result of KASPER, reporting of KASPER productivity in a variety of instances, including that of law enforcement, has increased 30-fold and investigative productivity has improved 5-fold.

In 2003, the Kentucky Legislature appropriated \$1.4 million to enhance the current KASPER system. The goals of the Enhanced KASPER, eKASPER system, are to automate the labor-intensive processes of report creation, reduce report distribution from a 4-hour goal to 15 minutes, and assure HIPAA compliance at all levels.

In 2004, the Kentucky General Assembly passed legislation that empowers the Cabinet to develop structures and processes with the KASPER system to study utilization trends, make referrals to law enforcement and regulatory bodies, and utilize KASPER reports in administrative hearings. It is our absolute intention to continue to refine and enhance our efforts in detecting and preventing prescription drug abuse and diversion in the Commonwealth. As I have discussed today, KASPER is a vital tool that plays a critical role in our efforts. KASPER is as useful for the physician as it is for the investigator. Of course, as it is the surgeon, not the scalpel, that saves the patient, ultimately these issues will only be solved by employing the skill and knowledge of individuals from a variety of fields. It is our belief that only a balanced and systemic approach that includes prevention, education, treatment, and enforcement will have a significant and sustainable positive impact on what has

become a very serious and insidious matter of public health and safety.

I appreciate your time and your interest in what I believe is a critical matter for the Commonwealth of Kentucky, as well as nationwide. Part of what we have been involved with recently has been a broad-scale, statewide drug control assessment summit that occurred this year under the auspices of our new Governor, Governor Ernie Fletcher, and our Lieutenant Governor, Steve Pence. Out of these, we are again working to develop statewide approaches to deal with a significant issue that particularly has great ramifications, I believe, for us from the point of view of not only public health but public policy.

I will be happy to answer any questions when the times comes, Senator. Thank you very much.

Senator SESSIONS. Thank you very much, Dr. Holsinger.

[The prepared statement of Dr. Holsinger follows:]

PREPARED STATEMENT OF JAMES W. HOLSINGER, JR., M.D.

Chairman Judd Gregg, and esteemed Members of the Senate Committee, I am here today to briefly discuss Kentucky's implementation of a Prescription Drug Monitoring Program (PMP), the status of the current system enhancements, and the goals of the Commonwealth in detecting and preventing prescription drug abuse and diversion.

Before I begin, I would like to thank and recognize Congressman Ed Whitfield who is passionate about wanting to work towards reducing the abuse of prescription drugs in the Commonwealth and beyond, and Congressman Hal Rogers, the Dean of Kentucky's Congressional delegation, for all of his hard work to reduce the abuse of prescription drugs.

There is no question, that prescription drug abuse and diversion is a public health crisis of great magnitude. Accordingly, failing to combat this issue with great vigor on multiple fronts, and in a highly coordinated fashion will undoubtedly lead to dire health and safety consequences nationwide.

Prescription Drug Monitoring Programs are designed to help prevent and detect the diversion and abuse of pharmaceutical controlled substances, particularly at the retail level. States that have implemented prescription monitoring programs have the capability to collect and analyze prescription data much more efficiently than States without such programs, where the collection of prescription information requires the manual review of pharmacy files, a time-consuming and invasive process.

The purpose of PMPs is to enhance the ability of health care professionals, as well as regulatory and law enforcement agencies, to collect and analyze controlled substance prescription data. This is accomplished by building a data collection and analysis system at the State level, enhancing existing programs' ability to analyze and use collected data, and facilitating the exchange of collected prescription data among States. The increased efficiency of prescription monitoring programs allows for the early detection of abuse trends and possible sources of diversion.

In your packet is a chart depicting the KASPER process, as well as some rather impressive statistical information generated from the program.

Kentucky's prescription drug monitoring program was established during the Kentucky General Assembly's 1998 Legislative Session, the provisions codified under KRS 218A.202. The program did not become operational until 1999.

The program is commonly referred to as KASPER which is the acronym for the Kentucky All Schedule Prescription Electronic Reporting program. This system automated the processing of data to support the tracking and sharing of information in accordance with existing statutes governing controlled substance prescriptions.

KASPER was created with two main goals in mind. First, to be a source of information for physicians and pharmacists; and second, to be an investigative tool for law enforcement. KASPER is the instrument that enables this information to be collected, analyzed, and shared rapidly.

Data gets into the relational database as dispensers transmit prescription data to our data collection agent by modem, diskette or tape. The data collection agent then verifies, compiles and sends the data to the Drug Enforcement and Professional Practices Branch, to be loaded into the KASPER server.

Very high security procedures protect access to the data with only Branch personnel having access to information within the KASPER database. Report requesting by authorized individuals also undergoes a high level of scrutiny. Release of data to anyone not authorized by Kentucky statute is a class D felony.

Currently, there are approximately thirty (30) States with some form of a PMP in operation although only Kentucky, Michigan and Nevada have electronic systems requiring the collection of data on all scheduled drugs. In Kentucky, the KASPER program is administered by the Cabinet for Health and Family Services' Office of Inspector General, Division of Fraud, Waste and Abuse/Identification and Prevention, Drug Enforcement and Professional Practices Branch. Controlled substance prescription reports (KASPER Reports) are available to Physicians—in the treatment of patients; Pharmacists—in the treatment of patients; Law Enforcement—in conjunction with a bona-fide investigation; Professional Licensure Boards—in investigation of their members; Medicaid Departments—for prevention of fraud and abuse; and by Grand Jury Subpoenas and Court Orders.

Many of the clinicians in the State were skeptical when KASPER was initiated. They felt the scrutiny implied by a monitoring program would interfere with their practice. In actuality, they have found that by utilizing the program to monitor their patients chronically utilizing controlled substances, they have documentation to prove they are treating these patients judiciously. Indeed, as a result of KASPER, reporting productivity has increased 30 fold and investigative productivity has improved 5 fold.

In 2003, the Kentucky State Legislature appropriated \$1.4M to enhance the current KASPER system. The goals of the Enhanced KASPER (eKASPER) system are to automate the labor-intensive processes of report creation, reduce report distribution from a 4-hour goal to 15 minutes, and assure HIPAA compliance at all levels.

In 2004, the Kentucky General Assembly passed legislation that empowers the Cabinet to develop structures and processes with the KASPER system to study utilization trends, make referrals to law enforcement and regulatory bodies, and utilize KASPER reports in administrative hearings. It is our absolute intention to continue to refine and enhance our efforts in detecting and preventing prescription drug abuse and diversion in the Commonwealth. As I have discussed today, KASPER is a vital tool that plays a critical role in our efforts. KASPER is as useful for the physician as it is for the investigator. Of course, as it is the surgeon, not the scalpel that saves the patient, ultimately these issues will only be solved by employing the skill and knowledge of individuals from a variety of fields. It is our belief that only a balanced and systemic approach that includes prevention, education, treatment, and enforcement will have a significant and sustainable positive impact on what has become a very serious and insidious matter of public health and safety.

Thank you for your time and interest in what I believe to be a very critical matter for the Commonwealth of Kentucky, as well as nationwide. I will be happy to answer any questions you may have.

Senator SESSIONS. Ms. Green?

Ms. GREEN. Thank you, Senator Sessions. I want to thank you and Members of the Committee for holding this hearing and allowing me to testify.

Since 1939, States have used prescription drug monitoring programs, or PMPs, as they are often called, to address prescription drug diversion and addiction. In addition to the 19 States currently operating in that they can respond to requests for information, 24 States are actively pursuing the establishment of a PMP; 15 of those States have Federal funds to do so.

Information collected through the system is already available to State regulatory and enforcement personnel under State law. Without the PMP, they collect information manually, going from pharmacy to pharmacy in order to gather all the necessary information for an investigation.

States often use these particular prescription monitoring programs, or PMPs, as early identification mechanisms. They use them to spot as early as possible a potential problem of diversion or addiction and then to timely refer information to the appropriate

medical professionals or State officials who can most appropriately address that particular problem.

Information is most often used to corroborate an existing investigation, to assist with the legitimate prescribing of controlled substances, to intervene as early as possible with patients who might be addicted, to actually confirm whether or not a particular claim against a prescriber/dispenser has a legitimate basis, and also as an indicator to initiate the manual investigation of a particular crime or doctor-shopping instance.

The States are actually actively seeking these particular programs primarily because right now those States with programs are seeing significant decreases in investigation of time. I know Kentucky, in addition to Nevada and Utah, are already indicating that they have as much as 80-percent decrease in investigation time needed to address the particular prescription diversion and addiction problem. They are also looking at possible instances of decrease in fraud, both in insurance and Medicare and other health care systems, and they are also starting to look at increased instances of referral to addiction treatment systems.

As it stands right now, there is a national evaluation design that is being drafted and will be finalized by the end of the year, with the idea of hopefully over the next year being able to scientifically document effectiveness of the programs, particularly improvements in the programs that might be needed, and also cost/benefits from the particular programs that are currently in use.

As it stands right now, one of the primary areas of focus for States with these programs and who are developing these programs is the particular impact of interstate issues, doctor-shopping in particular, in several States that are looking at developing the programs. That kind of interstate issue is impacting the dispensing and prescribing to these substances, and States are now trying to focus on how the particular prescription monitoring programs can be designed to address those interstate issues.

Senator, I want to thank you again for this opportunity to testify, and at the appropriate time I also am more than happy to answer any questions.

Senator SESSIONS. Thank you. Well said.

[The prepared statement of Ms. Green follows:]

PREPARED STATEMENT OF SHERRY GREEN

Chairman Gregg, Senator Sessions, Members of the Committee, and staff, thank you for this opportunity to appear before you today to offer an overview of State prescription drug monitoring programs (PMPs). I am honored to be here to discuss this issue at a time when Federal support for these programs and States' efforts to establish and enhance them has never been stronger.

Definition and Intent of Prescription Drug Monitoring Programs (PMP)

For those unfamiliar with prescription monitoring programs, I offer the following definition. A prescription monitoring program (PMP) is a system into which prescription data for designated schedules of controlled substances are reported dispensers to a central location (e.g., a State agency) where the information is entered into an electronic database. A PMP can perform three primary functions: (1) data collection, (2) respond to requests for reports by those authorized by statute/regulation/rule to make such requests, and (3) optimally, data would be analyzed to spot trends and identify diversion and addiction issues early with reports going proactively to those who could respond (e.g., physicians, pharmacists, occupational licensing, certification and regulatory personnel, law enforcement).

State PMPs can optimally accomplish a variety of goals related to safeguarding public health and safety. These purposes could include: to support the legitimate medical use of controlled substances; to facilitate and encourage the identification, intervention with and treatment of individuals addicted to prescription drugs; to identify and prevent drug diversion; to provide assistance to those investigating cases of diversion or other misuse; and to inform the public, including health care professionals and policy makers, of use and abuse trends related to prescription drugs (for more information regarding the possible missions of State prescription monitoring programs, please see *Prescription Monitoring Work Group of the National Alliance for Model State Drug Laws: Recommendations for State Prescription Monitoring Programs*, submitted with this testimony).

The data collected in the monitoring system is **not** “new” information—in other words, information that was previously unavailable to those investigating diversion cases. With or without a PMP in place, prescription information **is** accessible to regulatory and/or law enforcement personnel with open cases involving suspected diversion of prescription drugs. What the PMP does by serving as a central point of collecting this data and responding to authorized requests is to save the already limited resources of State regulatory boards and law enforcement by eliminating the need for their staff to go to individual pharmacies throughout the State in order to view the specific prescription data needed for diversion investigations.

NAMSDL’s History Assisting States re: PMPs

As a Congressionally-funded 501(c)(3) nonprofit organization, the National Alliance for Model State Drug Laws (NAMSDL) has worked with States to address alcohol and other drug problems through laws, policies, and programs, using the model laws created by NAMSDL’s predecessor—the President’s Commission on Model State Drug Laws—as a menu of options. Prescription drug misuse, abuse, diversion, and addiction have been among the issues on which States have sought NAMSDL’s assistance since our inception in 1993, including information and guidance in planning, establishing, and enhancing State PMPs. NAMSDL’s Congressional funding through the Transportation, Treasury, and General government (formerly Treasury, Postal, and General government) appropriations has permitted us to work with States on these issues, as well as over 70 other alcohol and other drug-related problems. Through a grant from the Bureau Justice Assistance (BJA), Office of Justice Programs, awarded in fiscal year 2003 (supplemented in fiscal year 2004), NAMSDL has been able to intensify efforts to assist States’ efforts to establish PMPs and to provide opportunities and instruments for planning for the interstate sharing of PMP data. Additionally, NAMSDL is now able to make outreach to States which have not historically pursued the possibility of a PMP as a tool for addressing the misuse of, abuse of, diversion of, and addiction to prescription drugs and for safeguarding the availability of these controlled substances to individuals with bona fide medical needs.

PMPs in the States

States Currently Operating Programs

As I testify before you today, 19 States are currently operating PMPs (i.e., these States have a monitoring system in place that is **both** collecting reports of the designated prescription data **and** responding to requests for information from those authorized to do so). These States are: California, Hawaii, Idaho, Illinois, Indiana, Kentucky, Maine, Massachusetts, Michigan, Nevada, New York, Oklahoma, Pennsylvania, Rhode Island, Texas, Utah, Virginia, Washington, and West Virginia.

A variety of State agencies house and operate these programs in the States, based on the resources, capabilities, purview, and other State-specific considerations as to where the PMP would be best suited in each State (for more discussion of factors States consider in determining which agency should house and operate a PMP, please see the report of NAMSDL’s national working group on State PMPs, submitted with this testimony). Of the 19 State PMPs currently in place, nine are housed and operated by State agencies responsible for public health, five by law enforcement/public safety departments, four by Boards of Pharmacy, and one—Maine—by the single State authority for substance abuse (a listing of the 19 current State PMPs and their overseeing agencies is provided with this testimony).

Projected Growth of State PMPs

In an effort to better address prescription drug misuse, abuse, diversion, and addiction, a significant number of States are mobilizing to establish PMPs. Wyoming and New Mexico are currently on track to being operating State PMPs by the end of calendar year 2004. With legislation in place, Alabama and Tennessee could be operating PMPs by early 2005. Iowa and Mississippi have determined that they can,

per their Controlled Substances Act, establish PMPs through rule changes by their Boards of Pharmacy; these changes are currently being pursued to ready these States to being operating monitoring systems. Additionally, the following 18 States are actively pursuing legislation/regulations/rules and/or planning the structure necessary to begin these programs: Colorado, Connecticut, Florida, Georgia, Kansas, Louisiana, New Jersey, Ohio, Oregon, Missouri, Montana, New Hampshire, North Carolina, North Dakota, South Carolina, South Dakota, Vermont, and Wisconsin. NAMSDDL continues to reach out with information and offers of technical assistance to the States that have not taken steps toward establishing PMPs or that are in the very nascent stages of planning.

Funding for State PMPs

Prior to fiscal year 2002, there were 15 States operating PMPs. States funded these programs as part of State agency budgets, fees from regulatory and/or licensing boards, private funding, or some combination of these funding streams. In fiscal year 2002, the Harold Rogers Prescription Drug Monitoring Program, a competitive grant program administered since fiscal year 2002 by the Bureau of Justice Assistance, Office of Justice Programs, was established to support State efforts to plan for, establish, and enhance PMPs. Since its inception, this funding opportunity has resulted in 14 States receiving new program grants and 6 States netting planning grants (a listing of States receiving these grants is provided with this testimony). To date, eight States have asked NAMSDDL staff about the possibility and timing of fiscal year 2005 Federal funding to assist in moving their efforts to establish programs forward. As we continue our outreach to States to engage them in planning efforts, this interest in Federal assistance is likely to rise.

Understanding that current Federal assistance is not intended to be used as operating or sustaining funding, States with planning and new program grants as well as those intending to apply for any fiscal year 2005 opportunities continue to develop options for funding the operations of State PMPs overtime. Private funding, pharmacy licensing fees, State appropriations, and State controlled substances registration fees are alternatives being considered by States for the continuing operation of new programs. Individuals working closely with existing PMPs and efforts to establish new monitoring systems are confident that evaluation of these programs will show cost benefits such as reducing Medicaid and healthcare fraud, diversion investigation time, and consequences related to untreated addiction to prescription drugs; these savings could result in an offset of funds being available to operate State PMPs and the continuation of these anticipated savings.

Components of a Strong Prescription Monitoring Program

I want to share NAMSDDL's observations of what appear to be key components of PMPs and their related enabling legislation and/or regulations/rules. While further formal evaluation of existing State PMPs across the Nation is needed, I hope that our anecdotal findings will be helpful in understanding the types of considerations that States may undertake in setting up these programs.

Schedules of Drugs Monitored

Drugs monitored optimally would include Federal controlled substances, additional specified controlled substances regulated by the State, and drugs of concern documented to demonstrate a potential for abuse, particularly those identified by law enforcement and addiction treatment professionals. While not officially scheduled, some substances can still be highly abused and require immediate attention. In a State which requires a legislative action to schedule substances, the prescription drug monitoring official will need the authority through the monitoring system to immediately address the problem. If the monitoring program only tracks controlled substances, the officials will have to wait perhaps 6 months or more for the legislature to pass a bill placing the abused substance on a controlled substances schedule.

Proactive Provision of Information

The monitoring system should proactively provide information to law enforcement, occupational licensing and other appropriate individuals. The prescription drug monitoring official should review the information in the system and if there is reasonable cause to believe there has been a violation of law or a breach of occupational standards, the official should notify the appropriate agency.

Additionally, the statute should allow the program to provide information for public research, policy and education purposes to the extent all information reasonably likely to reveal the patient or other person who is the subject of the information has been removed.

Individuals Allowed to Request Information from State PMPs

Dispensers and prescribers, law enforcement officials and occupational licensing officials should be included among the individuals or officials allowed to request specific information from the program.

Training for Individuals Utilizing State PMPs

Requestors of program information must demonstrate that they have the training necessary to responsibly and properly use the information they receive from the program. All requestors should be required to prove that they have received training on the purpose and operation of the program, and how to properly use the program. Additionally, health professionals should be required to receive training on proper prescribing practices, pharmacology and identification, treatment and referral of patients addicted to or abusing substances monitored by the program. This training can help physicians better assess whether the marketing and sales information they are given about a prescription drug's effects appears to be accurate.

Evaluation of State PMPs

An evaluation component is necessary to identify cost benefits of the program and any recommended improvements. As part of the ongoing assessment process, an advisory board or council should provide advice and input regarding the development and operation of the prescription drug monitoring system. The board or council should address issues such as (1) what drugs of concern to be monitored, (2) what specific State controlled substances to be monitored, (3) what constitutes diversion and proper prescribing, (4) the content and implementation of educational courses, (5) the interpretation of prescription monitoring information.

Confidentiality Provisions for PMP Data

Confidentiality protections from improper use of the system or of information from the system are important statutory provisions. Prescription monitoring information should not be subject to public or open records laws. Additionally, the law creating the prescription drug monitoring program should include penalties for knowingly disclosing or using information other than as authorized by the law.

Addressing Interstate Issues

Interstate misuse and abuse of prescription drugs is an issue each State with a prescription drug monitoring program should attempt to address. By statute, regulation or interstate agreement, the State should speak to the following circumstances:

- pharmacies or other dispensers located in the State with a prescription drug monitoring program which dispense or deliver to an address of an ultimate user in another State;
- pharmacies or other dispensers located in another State which dispense or deliver to an address of an ultimate user in the State with a prescription drug monitoring program;
- pharmacies or other dispensers located in another State which dispense or deliver to an ultimate user with an official address in the State with a prescription drug monitoring program.

Progress on Interstate Issues

An acknowledged challenge for States is addressing the diversion that can occur from State to State. In enhancing existing PMPs and in establishing new programs, States are working to include provisions for information sharing among States with monitoring systems in order to reduce interstate diversion. Here are several examples of current efforts:

Provisions for Mail Order Pharmacies

In a survey conducted by NAMSDL of existing State PMPs, 12 of the 19 existing PMPs indicated that they require out-of-State mail order pharmacies delivering or dispensing drugs into their States to report data to their States' PMPs (HI, ID, IL, IN, KY, ME, MI, NY, OK, RI, UT, WV). The reporting requirement is based on the license or registration which the mail order pharmacies must obtain to conduct business or dispense in their States. These measures can help reduce the incidents of "doctor shopping" across State lines in an effort to avoid detection by the monitoring system. A summary of NAMSDL's survey re: how State PMPs are addressing mail order pharmacies is submitted with this testimony.

Western States Network

Initiated by Nevada, the Western States Network is a plan to share PMP data among the States with PMPs in the Western U.S. (currently Nevada, Idaho, California, Oklahoma, and Texas) and Hawaii through a secure e-mail exchange. Nevada

is currently “beta” testing the online technology required before working with the other States in the region to establish legal agreements and then technology structures to begin the proposed data exchange.

Common Data Elements To Be Collected by State PMPs

To facilitate interstate sharing of PMP data, common data elements must be collected by each State with a monitoring system. This will allow for consistency in reporting as well as, from a technological standpoint, a cleaner transfer of data. The National Association of State Controlled Substances Authorities (NASCSA) and the Alliance of States with Prescription Monitoring Programs, based in part on a 2003 NASCSA survey of data that was being collected by State PMPs, convened a Prescription Monitoring Standards Working Group that recommended that States with and developing prescription monitoring systems include the following set of data elements:

- Dispenser identification number
- Date prescription filled
- Prescription number
- Whether the prescription is new or a refill
- NDC code for Controlled Substance dispensed
- Quantity of Controlled Substance dispensed
- Number of days’ supply of Controlled Substance
- Patient identification number
- Patient last name
- Patient first name
- Patient street address
- Patient city
- Patient State
- Patient postal code
- Patient date of birth
- Prescription identification number
- Date of prescription issued by practitioner
- Person who receives the prescription from the dispenser, if other than the patient
- Source of payment for prescription
- State issued serial number, if applicable.

NAMSDL has widely distributed these recommendations to States working to establish monitoring systems in an effort to encourage consistency among programs that will better facilitate interstate sharing. Additionally, NAMSDL includes members from NASCSA and Alliance of States members in our regional planning, topical working groups, and national meetings to keep all involved informed re: efforts in this area.

Legal Agreements Among States

In addition to establishing accommodating technology structures among States, legal agreements must be in place to allow the exchange of PMP data across State lines and among the entities housing the PMP and the entities requesting the information. Legal counsel working with NAMSDL on these issues suggests that these arrangements may resemble interstate commerce compacts that States currently utilize. NAMSDL has convened a national working group comprised of State administrators of PMPs, representatives from State attorneys general’s offices, public health officials, addiction treatment professionals, law enforcement officials, and physicians (including a pain management specialist) to offer their expertise and recommendations toward our drafting a model interstate compact. This model will offer a guide for States to use in establishing these legal agreements for sharing PMP data.

Internet Pharmacies

To date, three States (Arkansas, Nevada, and Florida) have State statutes in place addressing Internet pharmacies. Only one of these States—Nevada—currently has a PMP; NV’s Internet pharmacy law requires Internet pharmacies to report to the State’s PMP for controlled substances delivered into the State.

Most State PMP administrators agree that as important as it is to have legitimate Internet pharmacies report into State PMPs, the legal sites are not the primary issue. Illegal Internet sites that acquire and deliver controlled substances to individuals without prescriptions for these prescription drugs are of greater concern. Federal assistance on this issue, such as that proposed by Senator Gregg, will be appreciated by States to alleviate the misuse, abuse, diversion, and addiction to which these illegal sites contribute.

Technical Assistance Provided to States by NAMSDL re: PMPs

NAMSDL provides a variety of technical assistance to States as they plan for, establish, operate, and enhance prescription monitoring programs. In broad terms, the overarching goals of our services to States are (1) to engage States in efforts to establish PMPs, (2) to provide information, tools (e.g., model law, samples of grant applications, etc.), and referrals to minimize the State resources needed to begin efforts to implement monitoring systems, and (3) to maximize the Federal and State resources going toward State efforts by coordinating information and State-to-State assistance to eliminate inadvertent “reinvention of the wheel” as States implement, operate, or enhance these programs. Specific services include:

- Assistance in drafting enabling legislation.
- Facilitating regional planning session to further interstate planning.
- Providing information on current PMPs efforts to States planning to establish programs.
- Contacting States which have not yet mobilized to create PMPs and providing them start-up information.
- Bill status updates on States’ legislative efforts.
- Serving as a central point for articles, materials, and updates re: State PMPs.
- Bimonthly updates re: State efforts, materials available, related Congressional news, and other relevant information.
- Connecting key constituencies groups within and among the States to work on establishing PMPs.
- Holding an annual conference on PMPs.
- Convening topical working groups to develop model acts, reports, or other resources as needed by States to address issues related to PMPs.

While our current grant from BJA has allowed us to intensify our technical assistance to States, NAMSDL has worked with States re: PMPs and the related issues since our inception. If prescription drug diversion, misuse, abuse, and addiction continue to be priority areas for States, NAMSDL—as it has historically—will continue to include these issues in our work with States beyond the life of any grant or grant program.

Opportunities for Congressional, Federal Support

I want to conclude by briefly outlining some possible opportunities for Congress and/or the Federal Government to support States in their efforts to create, sustain, and enhance prescription monitoring programs. These suggestions come from feedback that NAMSDL has received from our State colleagues as we work with them on these programs.

Funding

Given the record budget deficits in many States at this time, it is unlikely that States will be able to establish new monitoring systems without the assistance of outside funding. Over the past few years, several State legislatures have actually passed the enabling legislation for State PMPs with fiscal notes attached, indicating that they recognized the need for and usefulness of these programs but cannot fund them through State budgets. The timing of the fiscal year 2004 grant solicitation and State pre-filing deadlines coincided, allowing a significant increase in the number of eligible States to apply and receive awards. Congressional support for similar grant opportunities will continue to facilitate the growth of these programs.

Internet Pharmacies

As I have previously mentioned in this testimony, States are concerned about the diversion of prescription drugs via illegal Internet sites. Federal assistance—specifically Federal-State partnerships—will be needed to effectively address this concern.

Federal Entities not Reporting to State PMPs

In NAMSDL’s work with States, they have alerted us to the dispensers of prescription drugs that are under Federal jurisdiction and thus not required to report to State PMPs: Veterans’ Administration hospitals and medical facilities, facilities on military bases, and tribal Nations. While these entities are housed in States, they are not required to report designated prescription data to State PMPs. States have indicated that it would be helpful toward further curbing diversion and intervening early with people who may need appropriate addiction treatment to have dispensers from these entities to report data to these programs.

Evaluation

Earlier in my remarks, I mentioned that there has not yet been a formal, science-based national evaluation of State PMPs. My understanding is that an evaluation design is being developed in conjunction with the BJA grant program. As more

States consider establishing programs and the existing 19 States plan for sustaining their current monitoring systems, objective, concrete results from this national evaluation re: the effectiveness of PMPs will greatly help States justify the expenditure for these programs. Currently, States must focus on the need for reducing prescription diversion and addiction as well as anecdotal findings/experiences from other States' monitoring systems when working with decision makers to establish or sustain State PMPs. With Federal resources also facilitating the start-up and enhancement of PMPs, this national evaluation will be instructive as to the best uses of these funds in the future (e.g., continued enhancements? technology project related to the PMPs? support to corollary systems such as addiction treatment?).

Thank you once again for the opportunity to share this information with you. I would be happy to answer any questions that you have as the hearing proceeds.

Senator SESSIONS. Dr. Varley, we are glad to have you here from Birmingham.

Dr. VARLEY. Thank you. I would like to thank you, Senator Sessions, and all of the Committee Members and staff for this opportunity to testify regarding prescription drug monitoring programs. I would also like to extend a special note of gratitude to you personally and your staff for your assistance in this matter.

I will sit here today in three capacities, the first as a representative and board member of the American Society of Interventional Pain Physicians. Our national organization represents nearly 50 percent of the 6,500 interventional pain physicians in America. Interventional pain management is that discipline of medicine devoted to the diagnosis and treatment of acute, sub-acute, and chronic pain and related disorders using interventional techniques in conjunction with other treatment modalities, including narcotic and psychotherapeutic medications. I would like to thank our national president, Dr. Lax Manchikanti, and our executive vice president, Dr. David Kloth, for their assistance in preparing this presentation.

The second capacity is as an interventional pain physician licensed to practice in the State of Alabama.

The third, and most important, as the father of three teenage girls, one of whom, Elizabeth, is present today to observe these proceedings.

My thoughts and prayers—

Senator SESSIONS. Maybe you would recognize her for us. Elizabeth? OK. I see her. We are glad you are here.

Dr. VARLEY [CONTINUING]. My thoughts and prayers are with those in Alabama and the Gulf Coast who are recovering from the devastation of Hurricane Ivan. The cost and destruction of Ivan, however, pales in comparison to the effect of prescription drug abuse and diversion in our society. I have provided supporting data and an extensive review in my formal presentation.

Today, chronic pain requiring treatment affects 10 to 30 percent of the population. Pain is second only to the common cold as the most frequent presenting complaint to a physician. Narcotic analgesics and psychotherapeutic medications made available through our pharmaceutical industry have brought the treatment of pain within our grasp. Congress in its wisdom saw fit in 1970 to pass the Controlled Substances Act to control the manufacture and distribution of pharmaceutical substances. Unfortunately, despite this legislation, the diversion of legitimately prescribed medications has become such a problem that John Walters, Director of the White House Office of National Drug Control, states that, "The

nonmedicinal use of prescription drugs has become an increasingly widespread and serious problem in this country, one that calls for immediate action.”

While most Americans recognize the risk of addiction and even death from illicit drugs, they are less likely to recognize the risks of prescription drugs. With increasing frequency, Americans have sought to divert prescription drugs for nonmedicinal purposes through theft, fraud, and forgery. With only 4.6 percent of the world’s population, the United States consumes 80 percent of the world’s opioid production. The problem of prescription drug diversion has eclipsed illicit drug use in public health and law enforcement challenge.

Eleven million persons abused psychotherapeutic or analgesic medications in 2003, second only to marijuana as the leading category of illicit drugs. The exponential rise of the diversion of controlled substances is best exemplified by the nonmedicinal use of OxyContin, a time-release pain killer similar to morphine. In 1997, 221,000 persons abused this drug, but by 2003 this number had grown to 2.8 million. Abuse of these drugs in the chronic pain population is estimated to be between 18 and 24 percent. The diversion of prescription medications cuts across all parts of society without regard for race, religious, gender, age, or national origin. Several years ago, I performed a routine urine drug screen on a 67-year-old male suffering from postsurgical back pain. I was prescribing OxyContin, 40 milligrams 3 times a day, but only methadone could be found in his urine. He was selling his OxyContin, which was paid for by his insurance company, and buying methadone, which is much cheaper, to control his pain. The profit amounted to a \$3,000-per-month supplement to his retirement income.

Although most of the 30 million chronic pain patients are honest, from 3 to 8 million persons a year are trying to deceive physicians and divert prescription drugs. Unfortunately, the availability of diverted prescriptions is no more apparent than in our schools. Evidence shows that drugs are available as early as middle school and there is widespread sale and use in high schools. We see tragic case after case of disrupted teenage lives with social and family strife often leading to mental health crises and, unfortunately, death from overdose or suicide.

The other end of the age spectrum was revealed in an article in the Birmingham News in May of this year. Two 66-year-old grandmothers were charged with 12 counts of illegal sale of prescription medications—morphine, OxyContin, and hydrocodone—within 3 miles of a school. The director of the local drug task force said, “The illegal use and sale of prescription medications has become one of the worst problems in [the county].”

Prescription drug use is a national problem. The DEA controls the manufacture and wholesale distribution of controlled pharmaceuticals through a nationwide database. The retail level, from the physician to the patient, however, is not constantly being monitored State by State, and there is virtually no system in place to aid physicians in identifying unscrupulous patients trying to obtain medications under false pretenses. Some 15 to 21 States have some form of State prescription drug monitoring system. A monitoring system alone, however, will not give physicians the timely informa-

tion needed to identify deceitful patients and stop diversion at its source. An effective monitoring system must be comprehensive, involving all 50 States, integrated, with all systems compatible and interconnected, involving all scheduled drugs and available in real time to give the physicians the information necessary to make good clinical decisions.

The American Society of Interventional Pain Physicians strongly supports NASPER, the National All Schedules Electronic Recording Act, which incorporates all these elements and has been tested and proven effective in Kentucky.

We ask that you support a system to give real-time, comprehensive information to physicians prescribing controlled substances. Help us put the control back into the Controlled Substances Act.

Thank you again for providing me the opportunity to present, and now I will be happy to answer any questions at the appropriate time.

Senator SESSIONS. Thank you, Dr. Varley, for that excellent testimony.

[The prepared statement of Dr. Varley follows:]

PREPARED STATEMENT OF KENNETH G. VARLEY, M.D.

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rise of the diversion of controlled substances is best exemplified by the non-medicinal use of Oxycontin (a time release pain killer similar to morphine). In 1997 221,000 persons abused this drug but by 2003 this number had grown to 2.8 million. Abuse of these drugs in the chronic pain population is estimated to be between 18 and 24 percent. The diversion of prescription medications cuts across all parts of society without regard for race, religion, gender, age or national origin. Several years ago I performed a routine urine drug screen on a 67 year old male suffering from post surgical back pain. I was prescribing Oxycontin 40 mg 3 times a day but only methadone could be found in his urine. He was selling his Oxycontin, which was paid for by his insurance company, and buying methadone, which is much cheaper, to control his pain. The profit amounted to a \$3,000 per month supplement to his retirement income.

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STATEMENT OF KENNETH G. VARLEY, M.D.

SUMMARY

PRESCRIPTION MONITORING PROGRAMS

1. The management of pain is becoming a high priority in the USA.
2. Controlled substance abuse and diversion is becoming a high priority.
3. Drug abuse and diversion as a national problem.
4. Drug abuse in chronic pain is a national problem.
5. Management of abuse and diversion of controlled substance is a public health issue.
6. Current state of affairs dictate the need for prescription monitoring programs.
7. Problems facing physicians, patients, and law enforcement.
8. The need for a comprehensive strategy to control drug abuse and diversion is increasing.
9. National versus State control of controlled substances.
10. A national program is feasible and cost-effective.

The **American Society of Interventional Pain Physicians** is an organization representing interventional pain physicians and other health care professionals involved in interventional pain management. Our membership is over 2,900 at the present time. It is estimated that there are 6,500 interventional pain physicians across the country practicing interventional pain management. Interventional pain

management, as per NUCC, is defined as—“the discipline of medicine devoted to the diagnosis and treatment of pain related disorders principally with the application of interventional techniques in managing subacute, chronic, persistent, and intractable pain, independently or in conjunction with other modalities of treatment.” As interventional pain physicians, our members are involved extensively in prescribing controlled substances, even though not to the same extent as non-interventional pain physicians whose mainstay of treatment of chronic pain is controlled substances.

1. The management of pain is becoming a high priority in the USA.

- Chronic pain is prevalent in 10 percent of the population by conservative estimates and as high as 30 percent by liberal estimates.
- In the last several years, health policy-makers, health professionals, regulators and the public have become increasingly interested in the provision of better pain therapies.
- The United States population (294,277,501) constitutes 4.6 percent of the world population (6,392,884,741).
- However, the United States with 4.6 percent of the world population consumes 80 percent of opioids from the world.
- Chronic pain involves multiple regions. After the initial onset of pain, more recent evidence shows that as many as 60 percent of the patients may continue to suffer with chronic pain after 1 year or even 12 years. This applies to children also.

2. Controlled substance abuse and diversion is becoming a high priority

- Non-medical uses of psychotherapeutics as described in multiple surveys include non-medical use of any prescription type:

- Pain relievers
- Tranquilizers
- Stimulants
- Sedatives

This category does not include over-the-counter substances.

- This interest in managing chronic pain has led to the explosion of prescription of controlled substances, fueled by:

- Pharmaceutical companies providing marketing and gifts.
- Numerous organizations providing guidelines and standards.
- Patient advocacy groups demanding opioids for benign pain.
- Enactment of Patient's Bill of Rights in many States.
- JCAHO regulations mandating monitoring and appropriate treatment of

pain.

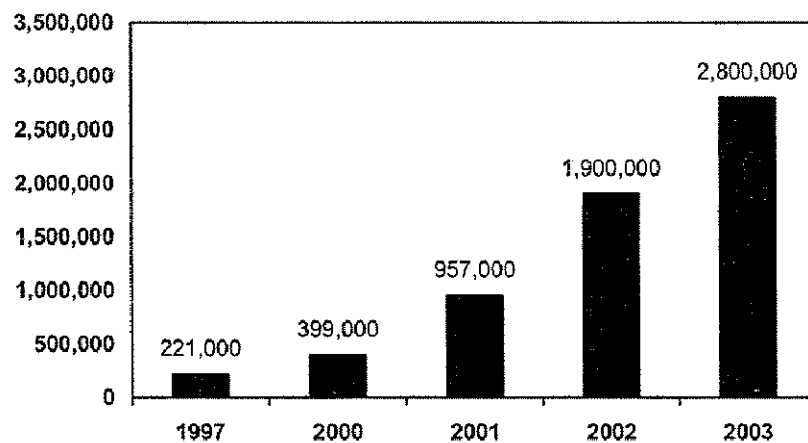
- Patient's right to pain relief.
- Easy availability on internet.
- Perception of safety of prescription drugs.
- While the true extent of prescription drug abuse and diversion is unknown, estimates from a national survey indicate that the principle drug of abuse for nearly 10 percent of U.S. patients in treatment is a prescription drug.
- The most commonly abused drugs include oxycodone (Percodan, Percocet, Roxicet, Tylox, OxyContin), hydrocodone (Vicodin, Vicoprofen, Lorcet, Lortab), hydromorphone, morphine (Astramorph, Duramorph, MS Contin, Roxanol), codeine, clonazepam (Klonopin), alprazolam (Xanax), lorazepam (Ativan), diazepam (Valium) and carisoprodol (Soma).¹
- Prescription drug abuse ranks second behind marijuana.
- John Walters, Director of the White House Office of National Drug Control Policy, said “the non-medical use of prescription drugs has become an increasingly widespread and serious problem in this country, one that calls for immediate action.”
- Emergency room visits resulting from the abuse of narcotic pain relievers have jumped 163 percent since 1995.
- The proposed 2005 budget from the White House for prescription drug diversion control will increase by \$20 million to \$138 million. Most of the funds will be directed at reducing the non-medical use of prescription drugs, mainly opioids.

3. Drug abuse and diversion as a national problem

Results from the 2003 National Survey on Drug Use and Health showed the following:

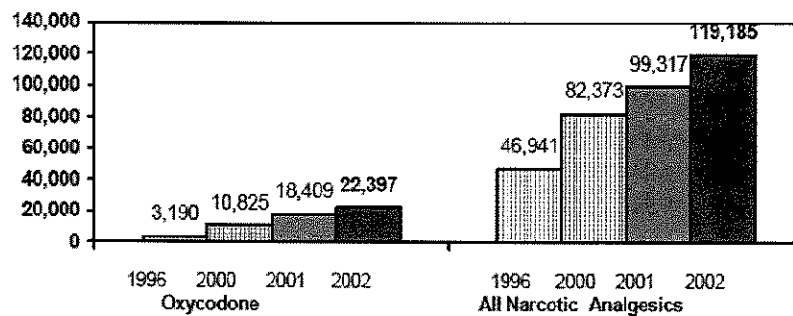
¹2003 National Survey on Drug Use and Health (NSDUH). Results from the 2003 National Survey on Drug Use and Health: National Findings. Department of Health and Human Services.

- An estimated 6.3 million persons were current users of psychotherapeutic drugs taken non-medically, representing 2.7 percent of the population aged 12 or older.
 - An estimated 4.7 million used pain relievers, 1.8 million used tranquilizers, 1.2 million used stimulants, and 0.3 million used sedatives.
 - Pain reliever use has increased from 4.4 million in 2002 to 4.7 million in 2003.
 - There was a significant increase in lifetime non-medical use of pain relievers between 2002 and 2003 among persons aged 12 or older, from 29.6 million to 31.2 million.
 - Specific pain relievers with statistically significant increase in lifetime use were hydrocodone products from 17.6 million in 2002 to 21.4 million in 2003.
 - Increases for OxyContin were from 1.9 million in 2002 to 2.8 million in 2003.
- The following shows gradual increase of OxyContin over the years.



Non-Medical use of OxyContin

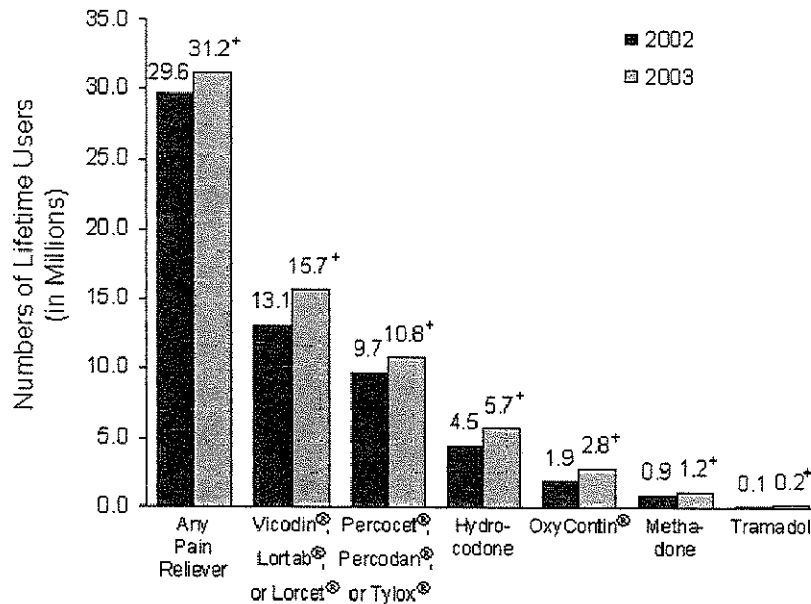
Estimated number of emergency department mentions for total coterminous United States from 1996 to 2003 increased substantially.



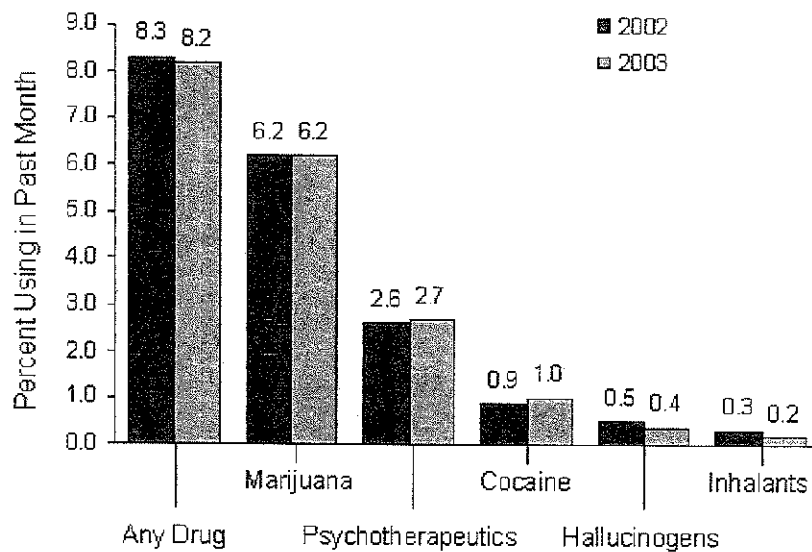
Estimated number of Hydrocodone and Oxycontin Emergency Department (DAWN ED) mentions for total coterminous United States: 1996-2002

- An estimated 18.2 percent of unemployed adults aged 18 or older were current illicit drug users in 2003 compared with 7.9 percent of those employed full-time and 10.7 percent of those employed part-time.
- Non-therapeutic use of pain reliever incidence increased from 1990 (573,000 initiates) to 2002 (2.5 million).

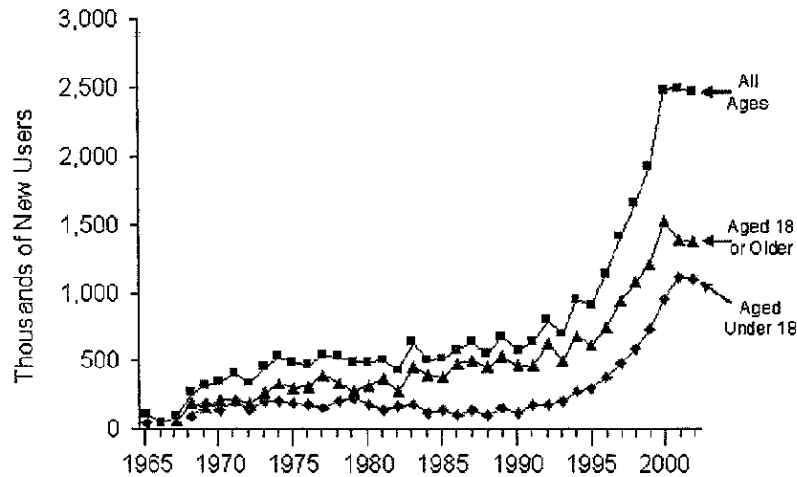
- There was a significant increase from 2002 to 2003 in the number of persons aged 12 or older with lifetime non-medical use of pain relievers, from 29.6 million to 31.2 million.



- There was an increase in past month non-medical use of pain relievers, from 4.1 percent in 2002 to 4.7 percent in 2003.



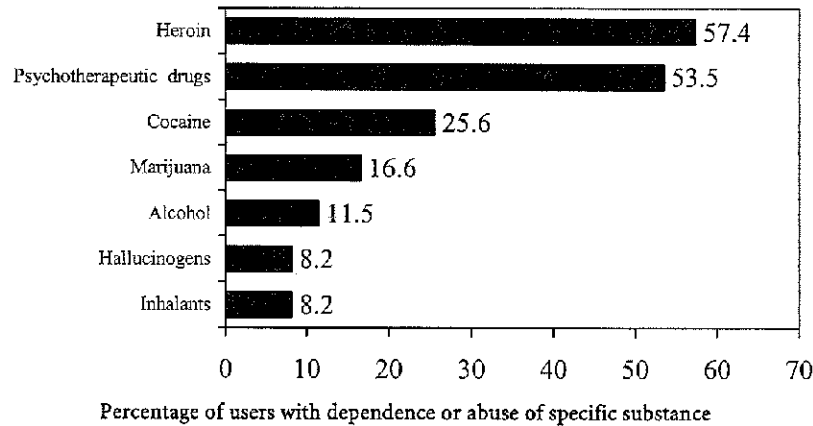
- New non-medical users of pain relievers have been increasing steadily since 1965 to 2002.



Annual Numbers of New Non-medical Users of Pain Relievers: 1965–2002

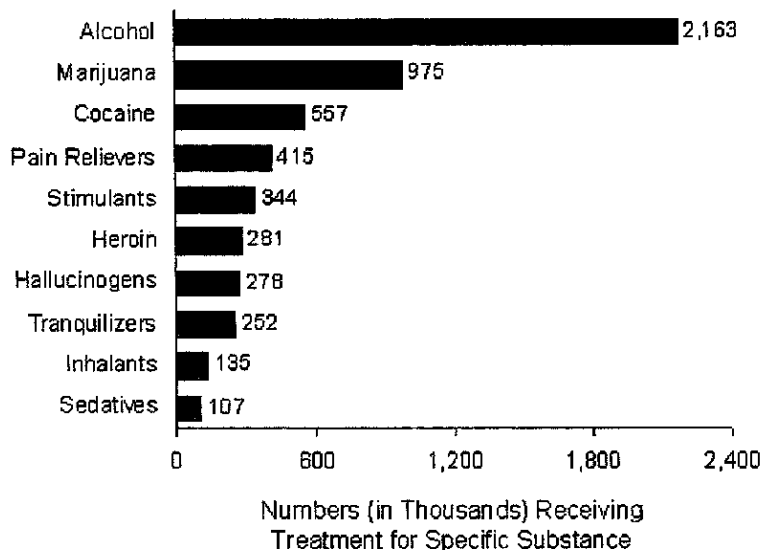
Source: 2003 National Survey on Drug Use and Health (NSDUH). Department of Health and Human Services

- The rate of current illicit drug use among youths aged 12 to 17 was 11.2 percent in 2003.
- Dependency or abuse of specific substances among past year users of substances is high for prescription drugs, second only to heroin.



Source: 2003 National Survey on Drug Use and Health (NSDUH). Department of Health and Human Services

- Treatment for substance for which persons aged 12 or older received treatment in the past year is high based on 2003 survey.



Source: 2003 National Survey on Drug Use and Health (NSDUH). Department of Health and Human Services

- Prevalence of mental illness is almost double in patients with drug abuse.

4. Drug abuse in chronic pain management is a national problem

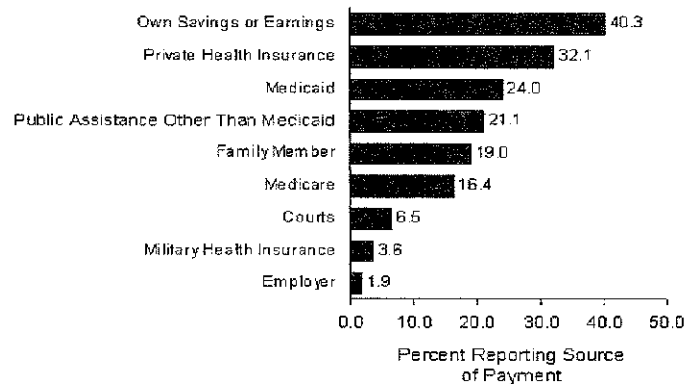
- The prevalence of chronic pain is estimated to be similar in all countries.
- Yet, the U.S. constituting 4.6 percent of the world population is consuming 80 percent of the opioids (Patricia Good—DEA Office of Diversion).
- An increasing number of studies have documented the relatively high incidence of controlled substance abuse and illicit drug use in patients undergoing treatment for chronic pain.
- The overall prevalence of controlled substance abuse in interventional pain management practice settings has been shown to be 18 percent to 24 percent.
- Overall, illicit drug use in chronic pain patients has been shown to be 14 percent to 16 percent in patients without controlled substance abuse, and 34 percent in patients with controlled substance abuse.
- With conservative estimates of chronic pain of 10 percent in the United States (approximately 20 to 25 million persons), the prescription drug abuse or misuse is seen in 18 percent to 24 percent (approximately 3 million to 8 million persons).
- Almost all (90 percent to 95 percent) of the patients presenting for evaluation in interventional pain management settings are already on heavy doses of controlled substances and we are unable to take them off of these drugs.

5. Management of abuse and diversion of controlled substance is a public health issue

- The diversion and abuse of prescription drugs are associated with incalculable costs to society in terms of addiction, overdose, death, and related criminal activities.
- The DEA has stated that the diversion and abuse of legitimately produced controlled pharmaceuticals constitute a multi-billion dollar illicit market nationwide.²
- As of February 2002, OxyContin has been involved in 464 deaths from prescription drug abuse, as reported by DEA on the basis of medical examiners autopsy findings for 2000 and 2001 from 32 States and increasing.
- Numerous methadone deaths have been reported.
- Patients may be receiving Schedule II, III, and IV prescriptions from multiple practitioners who are unaware of the potential for drug interactions or of the potential for abuse, and diversion of certain medications.

²Drug Enforcement Administration and the National Alliance for Model State Drug Laws, *A Closer Look at State Prescription Monitoring Programs* (<http://www.dea diversion.usdoj.gov/pubs/program/prescription-monitor/summary.htm>).

- Drug spending is skyrocketing. Significant amounts of Medicaid funds are spent on abused drugs. Drug spending in some States has increased by 65 percent in 2003.
- Source of payment for specialty treatment or drug abuse and addiction treatment is highest for Federal funds:



(Note that the estimates of treatment by source of payment include persons reporting more than one source.)
 Source: 2003 National Survey on Drug Use and Health (NSDUH). Department of Health and Human Services

- Projected economic cost of drug abuse for 1998 through 2000 has been shown by Levin group as 143.4 billion for 1998, 152.5 billion for 1999, and 160.7 billion for 2000.
- The Office of the National Drug Control Policy estimated the economic cost of drug abuse in the United States from 1992 to 1998 with overall cost of drug abuse to society increasing at a rate of 5.9 percent annually with healthcare costs of \$14.9 billion in 2000.
- A 1995 study by the Center on Addiction and Substance Abuse of the cost of substance abuse to Federal entitlement programs found that healthcare and disability costs alone were 17.6 billion, representing nearly 20 percent of the Federal healthcare budget. In this study, the cost to the Medicaid program resulting from substance abuse were enormous—in 1994, accounting for almost \$8 billion in Medicaid expenditures.
- A significant number of Medicaid recipients have been shown to abuse drugs varying from 9.4 percent to 16.14 percent in the Medicaid program, with prevalence of 15.5 percent functional impairment due to drug abuse.
- A 2004 study by the Luo et al. (*Spine* 2004) showed that there was an increased risk in women and patients of low economic status for non-medical use of psychotherapeutic drugs. These factors are important in Medicaid as the majority constitute women and men of low socioeconomic status.
- In a study performed by Manchikanti et al. (*Kentucky Medical Association Journal*—in press), patients on Medicaid as their primary insurance or in conjunction with Medicare showed significant incidence of drug abuse.
 - Patients covered by third party insurance showed 17 percent prevalence of illicit drug use, with patients on Medicare with or without third party insurance, showing 10 percent illicit drug use.
 - Patients on Medicare and Medicaid showed illicit drug use in 24 percent.
 - Patients only on Medicaid showed illicit drug use in 39 percent of the patients.
 - Combined use of illicit drugs and misuse of prescription drugs was seen in 60 percent of the patients only on Medicaid and 40 percent of the patients with Medicare and Medicaid.

6. Current state of affairs dictate the need for prescription monitoring programs

- The increasing diversion of prescription drugs for illegal use is a disturbing trend in the Nation's battle against drug use and abuse.
- Prescription drug diversion is the channeling of pharmaceuticals for illegal purposes or abuse. It can involve activities such as "doctor shopping" by individuals who visit numerous physicians to obtain multiple prescriptions, illegal sales of prescription drugs by physicians or pharmacists, and prescription forgery.

- States have recognized the need for monitoring of controlled substances since 1940 with implementation in California followed by Hawaii in 1943 (Table 1). Now, 15 States have such programs, which include California, Hawaii, Idaho, Illinois, Indiana, Kentucky, Massachusetts, Michigan, Nevada, New York, Oklahoma, Rhode Island, Texas, Utah, and Washington State.
- Florida and Virginia are actively pursuing such programs.
- GAO in its May 2002 report of State monitoring programs concluded that:
 - They indeed provide an efficient tool for stemming the growing problem of illegal diversion of prescription drugs.
 - They offer quick access to comprehensive information on drugs most likely to be abused and deter abusers from doctor shopping within the State.
 - Incidences of drug diversion, however, are on the rise in neighboring States, indicating the problem is proliferating or shifting to States without monitoring programs.
 - The programs have helped reduce availability of abused drugs in Kentucky, Nevada, and Utah.
- State prescription monitoring programs reduce expenses to healthcare officials, pharmacists, and law enforcement officials.
- State programs have helped shorten investigation time and reduce illegal drug diversion.

7. Problems facing physicians, patients and law enforcement

i. Problems facing physicians

- Every day a physician has to consider:
 - Litigation for failure to treat pain
 - Litigation for undertreatment
 - Criminal charges for abuse, addiction, or death
 - Numerous Federal regulations
 - State Board of Medical Examiners
 - Drug Enforcement Agency
 - State Bureau of Narcotics
 - State Board of Pharmacy
- Problems in Alabama
 - Based on the DEA fact sheet of 2004, Alabama continues to see an increase in diverted pharmaceuticals across the State.
 - OxyContin is still the number one pharmaceutical drug abused across the State.
 - The sale and production of Vicodin has increased in recent years slightly, along with the illegal use of the drug.
 - In addition, current intelligence and investigations indicate that Alabama is a major market for Dilaudid. Distribution in Alabama has increased due to the fact that the price of heroin in the New York area has fallen dramatically causing the bottom to fall out of the market for Dilaudid. Distribution organizations are targeting the metropolitan areas of Alabama, as the price they receive for Dilaudid is higher in Alabama than in the source areas.
- Options for Physicians:
 - Referral to Pain Medicine Clinics
 - Clinics with mainstay treatment of opioids
 - Very limited resource
 - Rare option for Interventional Pain Specialists
 - Refuse to Prescribe Controlled Substances
 - Not an option for many practices
 - Inadequate treatment of pain lawsuits
 - Litigation for addiction
 - Criminal charges of murder
 - Surrender Schedule II DEA License
 - Lose many patients
 - Lose hospital privileges
 - Lose all insurance patients
 - Not an option for interventionalists
- Benefits for Physicians:
 - NASPER could alert physicians about patients who are drug shopping.
 - Physician can make more informed decisions on prescribing, leading to less risk for medical license.
 - Decreased hassle factor with DEA, Medical Board and U.S. Attorneys.

ii. Problems facing patients

- Undertreatment of pain
- Suspicion may not be resolved

- Patients who are drug shopping will benefit from physician intervention.
- Patients who are not drug shopping will benefit from physician ability to feel more comfortable in prescribing medicines they need.
- Benefits for Patients:
 - Improved access
 - Stable patient-physician relationship

iii. Law Enforcement

- Court cases involving possession and trafficking in controlled substances is increasing rapidly across the Nation.
- In one county in Eastern Kentucky, a 350 percent increase was noted in 4 years.
- Law enforcement officials are reporting an increasing number of DUIs related to drugs than to alcohol.
- Substance abuse residential houses are not able to cope with the number of patients on drugs.
- More than 1 in 10 inmates have been committed due to an offense related to drugs.
- The DEA, medical boards, and other authorities are struggling to contain drug abuse and related consequences.
- NASPER will benefit not only patients and physicians by improving access to care and improving the quality of care but also will assist law enforcement by punishing the trafficking patients, and physicians who inappropriately prescribe or abuse drugs.

8. The need for a comprehensive strategy to control drug abuse and diversion is increasing

While State programs have been effective, the following deficiencies have been noted:

- From 1940 to 1999, States have been able to establish only 15 functioning programs. The number of States with prescription drug monitoring programs has grown only slightly over the past decade, from 10 in 1992 to 15 in 2002.
- The White House estimates to increase drug monitoring programs by 10 next year.
- The nationwide number of prescription drug monitoring programs has been changing. West Virginia terminated its program in 1998, but enacted legislation in 2002 to create a new program. New Mexico terminated its program in 2000 (Figure 1).
- Even though the 15 programs have a common goal of reducing prescription drug diversion and abuse, they vary in their objectives, design, and operation.
- The major purpose of the State programs is to help law enforcement identify and prevent prescription drug diversion.
- Education objectives to provide information to physicians, pharmacies, and the public is a secondary objective.
- Very few States are proactive to the extent that physicians can access the information proactively to reduce or prevent abuse and diversion.
- Program design also varies across States, in terms of which drugs are covered, how prescription information is collected and which agency is given responsibility for the program.
- Methods for analyzing the data to detect potential diversion activity also differ among States.
- Only 4 of 15 States monitor Schedule IV drugs and only 5 of 15 monitor Schedule III drugs which are the subject of major-controlled substance abuse.
- Challenges exist in establishing and expanding State programs, due to lack of awareness of the extent to which prescription drug abuse and diversion is a significant public health and law enforcement problem.
- Extent of diversion in abuse is not always recognized by the States.
- National efforts have focused only on providing guidance and technical assistance.
- Incidents of drug diversion, however, are on the rise in neighboring States, indicating the problem is proliferating or shifting to States without monitoring programs.

9. Federal versus State control of controlled substances

i. Federal

- Controlled Substances Act. The Controlled Substances Act established a classification structure for drugs and chemicals used in the manufacture of drugs that are designed as controlled substances.

- FDA regulations of prescription drugs. The FDA is responsible for ensuring that all new drugs are safe and effective.
- The DEA's regulation of controlled substances. The DEA is the primary Federal agency responsible for enforcing the Controlled Substances Act. The DEA has the authority to regulate transactions involving the sale and distribution of controlled substances at the manufacturer and wholesale distributor levels.
- Guidelines for marketing drugs to healthcare professionals. In April 2003, HHS's Office of Inspector General issued voluntary guidelines for how drug companies should market and promote their products to Federal healthcare programs. Federal funds are spent through Medicare/Medicaid military health and other assistance programs spent by patients in acquiring drugs and also in drug treatment.
- Federal funds utilized for management diversion. Thus, drugs are mostly controlled by Federal agencies rather than State agencies.

ii. State

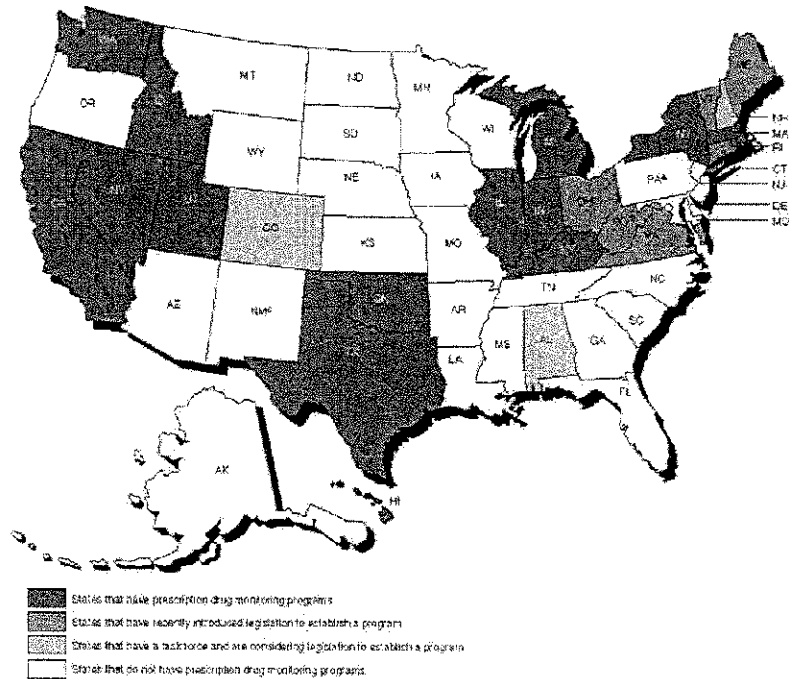
- The State's regulation of practice of medicine and pharmacy and role in monitoring illegal use and diversion of prescription drugs. State laws govern the prescribing and dispensing of prescription drugs by licensed healthcare professionals.
- Multiple State agencies have responded to reports of drug abuse. However, complete information is not available from the directors of State Medicaid fraud control units in Kentucky, Maryland, Pennsylvania, Virginia, and West Virginia. They stated that drug abuse and diversion of OxyContin is a problem in these States.
- State Medical Licensure Boards have also responded to complaints about physicians who were suspected of abuse and diversion of controlled substances, but like the Medicaid Fraud Control Units, the Boards generally do not maintain data on the number of investigations that were involved.
- Although Medical Boards may be tough, they can't always catch the bad apples.
- Kentucky's Board of Medical Licensure ranked fifth in the Nation for disciplining physicians in 2001.
- Board reacts to complaints and can't statutorily look for problems on its own.

In contrast, the DEA has statistics available on drug abuse and diversion. Overall, Federal control and responsibility outweighs States.

10. A national program is feasible and cost-effective

- The cost of the program in each State varies according to differences in their design and operational factors.
 - Confidentiality appears to be a major concern. Both physicians who legitimately prescribe prescription drugs and patients who legitimately use them are concerned that the information collected, maintained, and monitored by State programs may be used inappropriately or compromised.
 - All States, regardless of whether there is a State prescription monitoring program or not, have the authority under their laws to conduct investigations of the records of individuals alleged to be involved in prescription drug diversion and abuse, including the records of prescribing physicians and dispensing pharmacies.
 - According to GAO, securing program funding is a critical challenge. The 2002 report states that according to officials from the National Alliance for Model State Drug Laws, the National Association of Drug Diversion investigators, and the DEA, securing program funding is a critical challenge faced by States that choose to develop, maintain, or expand a prescription drug monitoring program.
 - A national comprehensive program with individual State authority with communication among programs with uniform data collection dispersion and ability for physicians to access the data will reduce drug abuse and diversion and at the same time, provide appropriate pain management. There are approximately 60,000 pharmacies across the United States covering half a million prescriptions per year.
 - A national program with a collection of State programs will be cost effective.
- Table 2** shows the contiguous States for each of the 50 States.
- As per the available data from the 2002 GAO report, describing key features of selected State prescription drug monitoring programs as shown in **Table 3**, the set of funding was \$415,000 in Kentucky, \$134,000 in Nevada, and \$50,000 in Utah. The annual operating costs consecutively for the 3 States was \$500,000, \$112,000 and \$150,000.

Figure 1: Status of Prescription Drug Monitoring Programs, by State, April 2002



*Pennsylvania does not have a PDMP, but requires pharmacists to submit data to the state attorney general's office.

*West Virginia terminated its PDMP in 1996 and has enacted legislation in 2002 to create a new program.

*New Mexico terminated its PDMP in 2000.

Source: National Alliance for State Model Drug Laws, 2002, and discussions with officials in New Mexico, Pennsylvania, and West Virginia.

TABLE 1. CHARACTERISTICS OF STATE PRESCRIPTION DRUG MONITORING PROGRAMS

State	Year Implemented	Controlled substance schedule(s) monitored	Type of monitoring system	Administrative Agency
California ^a	1940	II	Electronic and triplicate form ^b	Pharmacy and law enforcement.
Hawaii	1943	II	Electronic	Law enforcement.
Idaho	1967	II, III, and IV.	Electronic	Pharmacy board.
Illinois	1961	II	Electronic	Public health.
Indiana	1995	II	Electronic	Law enforcement.
Kentucky	1999	II, III, IV and V.	Electronic	Public health.

TABLE 1. CHARACTERISTICS OF STATE PRESCRIPTION DRUG MONITORING PROGRAMS—CONTINUED

State	Year Implemented	Controlled substance schedule(s) monitored	Type of monitoring system	Administrative Agency
Massachusetts	1992	II	Electronic	Public health.
Michigan ^c	1989	II	Single form.	Commerce.
Nevada	1997	II, III, and IV.	Electronic	Pharmacy board and law enforcement.
New York ^d	1977	II	Electronic	Public health.
Oklahoma	1991	II	Electronic	Law enforcement.
Rhode Island	1979	II, III	Electronic	Public health.
Texas ^e	1982	II	Electronic	Law enforcement.
Utah	1997	II, III, IV, and V.	Electronic	Commerce's Licensing Division.
Washington ^f	1987	Determined by disciplinary authority.	Triplicate form ^b .	Public health.

^a California is currently testing an electronic monitoring program for Schedule II controlled substances. Until the pilot program is completed on July 1, 2003, pharmacies will also have to continue submitting copies of the triplicate forms to the State monitoring agency.

^b A triplicate prescription form is a paper prescription form issued by the State to prescribers, who must use it when writing prescriptions for covered controlled substances. The prescriber keeps one copy after writing the prescription, and the pharmacist keeps a copy when the prescription is filled and sends the third copy to the state PDMP.

^c In 2001, Michigan enacted legislation to convert its PDMP to an electronic monitoring program. Until the new electronic system is implemented, the program will continue to require pharmacies to submit copies of State-issued official prescription forms for schedule II controlled substances.

^d As of January 1, 2002, New York switched to an electronic monitoring system from a paper-based system using a triplicate form. The new electronic system is supplemented by a State-issued, single-copy prescription form that includes a number of security features to prevent counterfeits.

^e Beginning in September 1999, Texas permitted pharmacies to submit prescription data electronically rather than submitting paper copies of prescription forms. In March 2002, Texas switched from triplicate to single-copy forms with a number of security features to prevent counterfeits. The requirement to submit prescription forms to the State agency will continue until the electronic system is fully implemented.

^f The Washington program applies only to licensed practitioners whose prescribing practices require monitoring because of the past drug abuse or inappropriate prescribing. The drugs the program covers vary, depending on the prescriber, from one controlled substance to all prescriptions.

Source: National Alliance for Model State Drug Laws. Information is current through February 4, 2002.

TABLE 2. SHOWS THE CONTIGUOUS STATES FOR EACH OF THE 50 STATES

State	Surrounding States
Alabama	Florida, Georgia, Mississippi, Tennessee.
Alaska	None.
Arizona	California, Colorado, New Mexico, Nevada, Utah.
Arkansas	Louisiana, Missouri, Mississippi, Oklahoma, Tennessee, Texas.
California	Arizona, Nevada, Oregon.
Colorado	Arizona, Kansas, Nebraska, New Mexico, Oklahoma, Utah, Wyoming.
Connecticut	Massachusetts, New York, Rhode Island.
Delaware	Maryland, New Jersey, Pennsylvania.
Washington DC	Maryland, Virginia.
Florida	Alabama, Georgia.
Georgia	Alabama, Florida, North Carolina, South Carolina, Tennessee.
Hawaii	None.
Idaho	Montana, Nevada, Oregon, Utah, Washington, Wyoming.

**TABLE 2. SHOWS THE CONTIGUOUS STATES FOR EACH OF THE 50 STATES—
CONTINUED**

State	Surrounding States
Illinois	Iowa, Indiana, Kentucky, Missouri, Wisconsin.
Indiana	Illinois, Kentucky, Michigan, Ohio.
Iowa	Illinois, Minnesota, Missouri, Nebraska, South Dakota, Wisconsin.
Kansas	Colorado, Missouri, Nebraska, Oklahoma.
Kentucky	Illinois, Indiana, Missouri, Ohio, Tennessee, Virginia, West Virginia.
Louisiana	Arkansas, Mississippi, Texas.
Maine	New Hampshire.
Maryland	District Of Columbia, Delaware, Pennsylvania, Virginia, West Virginia.
Massachusetts	Connecticut, New Hampshire, New York, Rhode Island, Vermont.
Michigan	Indiana, Ohio, Wisconsin.
Minnesota	Iowa, North Dakota, South Dakota, Wisconsin.
Mississippi	Alabama, Arkansas, Louisiana, Tennessee.
Missouri	Arkansas, Iowa, Illinois, Kansas, Kentucky, Nebraska, Oklahoma, Tennessee.
Montana	Idaho, North Dakota, South Dakota, Wyoming.
Nebraska	Colorado, Iowa, Kansas, Missouri, South Dakota, Wyoming.
Nevada	Arizona, California, Idaho, Oregon, Utah.
New Hampshire	Massachusetts, Maine, Vermont.
New Jersey	Delaware, New York, Pennsylvania.
New Mexico	Arizona, Colorado, Oklahoma, Texas, Utah.
New York	Connecticut, Massachusetts, New Jersey, Pennsylvania, Vermont.
North Carolina	Georgia, South Carolina, Tennessee, Virginia.
North Dakota	Minnesota, Montana, South Dakota.
Ohio	Indiana, Kentucky, Michigan, Pennsylvania, West Virginia.
Oklahoma	Arkansas, Colorado, Kansas, Missouri, New Mexico, Texas.
Oregon	California, Idaho, Nevada, Washington.
Pennsylvania	Delaware, Maryland, New Jersey, New York, Ohio, West Virginia.
Rhode Island	Connecticut, Massachusetts.
South Carolina	Georgia, North Carolina.
South Dakota	Iowa, Minnesota, Montana, North Dakota, Nebraska, Wyoming.
Tennessee	Alabama, Arkansas, Georgia, Kentucky, Missouri, Mississippi, North Carolina, Virginia.
Texas	Arkansas, Louisiana, New Mexico, Oklahoma.
Utah	Arizona, Colorado, Idaho, New Mexico, Nevada, Wyoming.
Vermont	Massachusetts, New Hampshire, New York.
Virginia	District Of Columbia, Kentucky, Maryland, North Carolina, Tennessee, West Virginia.
Washington	Idaho, Oregon.
West Virginia	Kentucky, Maryland, Ohio, Pennsylvania, Virginia.
Wisconsin	Iowa, Illinois, Michigan, Minnesota.
Wyoming	Colorado, Idaho, Montana, Nebraska, South Dakota, Utah.

**TABLE 3. KEY FEATURES OF SELECTED STATE PRESCRIPTION DRUG
MONITORING PROGRAMS**

Key features	Kentucky	Nevada	Utah
Census 2000 population	4.04 million	1.99 million	2.23 million.
Year operational	1999	1997	1997.
Start-up funding	\$415,000 in Federal start-up grant funds.	\$134,000 ^a in State funds.	\$50,000 in one time State funds.
Controlled substance schedules monitored	II, III, IV, V	II, III, IV	II, III, IV, V.
Electronic data collection and reporting	Yes	Yes	Yes.
Private contractor receives dispensing information and creates database.	Yes	Yes	No.
Annual operating costs (estimate)	\$500,000	\$112,000	\$150,000.

TABLE 3. KEY FEATURES OF SELECTED STATE PRESCRIPTION DRUG MONITORING PROGRAMS—CONTINUED

Key features	Kentucky	Nevada	Utah
Staff	4 full-time (1 licensed pharmacist investigator, 2 pharmacy technicians, 1 data entry operator) and 4 part-time.	1 full-time with all administrative duties.	3 full-time including manager and 2 support staff.
Number of pharmacies reporting dispensing data (estimate).	1,300	387	375.
Number of daily data requests received (estimate)	400	20	130 to 150.
Report turnaround time to requestor (estimate)	4 hours	4 hours	3 hours.
Penalty for unauthorized use or disclosure of PDMP data	Class D felony ^b	PDMP statute has no penalty.	Third-degree felony. ^c

^a Nevada received \$265,000 for the first 2 years of its program's operations, including 2-year grants from two pharmaceutical companies and the State board of medical examiners.

^b Kentucky law defines a class D felony as one carrying a sentence of at least 1 year, but not more than 5 years in prison.

^c Utah law defines a third-degree felony as one carrying a sentence of not more than 5 years in prison.

Source: GAO interviews with PDMP administrators.

Senator SESSIONS. Ms. Pritts, get that microphone there, and we would be delighted to hear from you at this time.

Ms. PRITTS. Good afternoon, Senator Sessions. I would like to thank you and the committee for inviting me here to testify today about the privacy considerations of prescription drug monitoring programs.

As we have heard from earlier witnesses, there is growing support for some Federal support for comprehensive and compatible State prescription drug monitoring programs. This is an admirable goal, and it appears that the State-based programs have been fairly successful in actually reducing prescription drug diversion and abuse. However, it is crucial to have adequate privacy protections in place as we look to expand these programs and to electronically link them.

My written testimony goes into quite a bit of detail about what Federal standards should look like if the Federal Government decides to support these programs through funding. There should be minimum Federal standards. Many States already have privacy protections in their State laws, but they do vary from State to State. If you are looking to share information across State lines, protections should be somewhat at least at a minimum level across the board.

Now, the reason why this is necessary is that HIPAA and other Federal privacy statutes generally do not cover prescription drug monitoring programs. There often is a misconception that the HIPAA privacy rule covers most people who hold and maintain medical information, but that is not the case.

My written testimony goes into the specific types of standards that States should be required to follow if they would request Federal funding, including notice; an individual's right of access to their own information; a right to correct that information if it is inaccurate, which is particularly important when you are talking about this type of information; restrictions on disclosures for recipients of information, this is an area that actually is lacking at the State level.

Perhaps, however, one of the largest privacy issues that I see arising from this whole circumstance is the manner in which identifiable data is transmitted and stored. The system that seems to be developing seems to be based on these large databases, either at the State level or there is some thought of even kind of a regional level if States elect not to participate in the system.

Maintaining data in this format has been seen by many people in the security field as being problematic, and it is problematic both in principle and in practice.

In principle, there are a lot of citizens in the United States who have a visceral negative reaction to government collecting and storing information in a central database. Florida is a perfectly good example of that. The Florida Legislature earlier this year tried and failed to pass a prescription drug monitoring bill which included a central database. The opponents compared the proposed database to databases maintained by communist Cuba. Now, these comments were not made by just your ordinary citizens. This particular comment came from one of the Republican Representatives. So you can see that there are very strong feelings on this issue by a number of the population, and linking data and having a comprehensive database will have to overcome those feelings in order to be successful.

Those feelings are not just based in principle, however. There are, as a matter of practice, some serious problems with maintaining data in this type of database. And, unfortunately, I am going to have to use Florida again as an example here. In the mid-1990s, using a similar database, in Florida doctors are required to report by name people who have been diagnosed with AIDS, and that data is maintained in a database with identifiable information. The patient's name, for example, is associated with it. And a county employee downloaded 4,000 names of AIDS patients, put them on a diskette, and was using it for his own personal dating purposes and also was basically threatening blackmail to release it to the newspapers.

When you have information that is concentrated in this type of a database, particularly depending on what kind of identifiers you might have associated with it, it becomes a very large temptation for people to act badly, not only hackers but people who have authorized access to the information.

One of the ways that they have gotten around this issue in the actual health care practice right now is to encrypt the data or to have certain types of linking done. I am not a technology expert, but I have heard presentations given, particularly by Dr. John Halamka, who runs the New England Health Electronic Data Interchange Network, and they have a system there that does not require the use—you can identify people on a need-to-know basis, but the information is not stored using identifiers that are easily picked out by people who would improperly access the system or improperly want to use the system.

So I would urge as we go forward here that some of these alternative technologies be considered. Oftentimes what happens in this field is that we start down one path, technology changes, and there has been a lot of commitment and money to one path, and so people are reluctant to change. And I do appreciate that. But to the

extent that there is an opportunity to think of other ways of doing things, this would be a good time to start those thought processes.

Adopting these kinds of privacy protections, including encrypting data or storing it in a nonidentifiable basis, will ease some of the privacy concerns that people have over establishing these programs and may ease the road into going forward in this area.

Thank you.

Senator SESSIONS. Thank you very much. You raise some matters that we need to discuss.

[The prepared statement of Ms. Pritts follows:]

PREPARED STATEMENT OF JOY L. PRITTS, J.D.

I. Introduction

Mr. Chairman and Members of the Committee on Health, Education, Labor, and Pensions: Thank you for the opportunity to testify before you today on the need for adequate privacy protections in prescription drug monitoring programs.

My name is Joy Pritts. I am an assistant research professor at Georgetown University's Health Policy Institute. My work at Georgetown focuses on laws, policies, and practices related to the privacy of medical information.

The non-medical use of prescription drugs continues to be a widespread and serious problem in this country. As part of the effort to control the illegal diversion of prescription drugs, many States have instituted prescription drug monitoring programs. These programs collect, review, and analyze identifiable prescription data from pharmacies. Although the programs differ in terms of objectives, design, and operation, they generally analyze and distribute collected information to medical practitioners, pharmacies, and regulatory and law enforcement agencies.¹ Many of these programs have been successful at reducing diversion within their States. It is not surprising that expanding the number of State prescription drug monitoring programs and ensuring that they are able to share data across State lines are key elements of the Federal strategy to reduce prescription drug abuse nationwide.²

While the goals of these programs are admirable, increasing the number of prescription drug monitoring programs that are able to share identifiable information electronically raises serious privacy concerns. Millions of Americans suffer from chronic pain. Without adequate privacy safeguards, patients will not seek treatment and practitioners will be hesitant to adequately prescribe medication.³ Absent strong privacy protections, there may well be wide-spread public resistance to linking prescription drug monitoring program data.

II. There Should Be Federal Privacy Standards for Prescription Drug Monitoring Programs

Federal proposals to encourage the expansion and linkage of State prescription drug monitoring programs should establish minimum, uniform privacy standards for these programs based on well-established fair information practice principles. Federal privacy standards for prescription drug monitoring programs are essential because these programs generally are not subject to the Federal Privacy Rule issued under the Health Insurance Portability and Accountability Act of 1996 (HIPAA Privacy Rule). The Privacy Rule only governs three major categories of entities that maintain identifiable health information called "covered entities": health care providers; health care clearinghouses; and health plans.⁴ Most State programs are administered by a State board of pharmacy, a State department of health, or a State law enforcement agency. As a general rule, these entities are not subject to the restrictions imposed by the HIPAA Privacy Rule.

While States generally have some privacy protections for prescription drug monitoring program data, these protections can vary widely from State to State. For example, some States impose a criminal penalty for unauthorized use or disclosure of prescription drug monitoring program information and others do not. Linking data between States with differing standards can result in decreased privacy protections

¹ See U.S. General Accounting Office, *Prescription Drugs: State Monitoring Programs Provide Useful Tool to Reduce Diversion*, GAO-02-634 (Washington, D.C. May 17, 2002).

² See the White House, *National Drug Control Strategy* (March 2004) available online at www.whitehousedrugpolicy.gov/publications/policy/ndcs04/index.html.

³ See Gao, *Prescription Drugs: State Monitoring Programs at 5*.

⁴ 45 C.F.R. §164.500 (applicability of Privacy Rule to covered entities) and 160.103 (defining covered entity).

for citizens of States with stringent privacy laws. Citizens should not lose privacy protections as a result of States' sharing data. As a practical matter, States with high privacy standards may be reluctant to share data with States that have less privacy protections.

Establishing Federal minimum privacy standards for prescription drug monitoring programs can help ease these concerns. While States should remain the primary regulators of prescription drug monitoring programs, any Federal funds for such programs should be tied to the requirement that State programs meet minimum Federal privacy standards. States should remain free to impose higher privacy standards to meet the particular needs of their citizens.

At a minimum such Federal standards should:

- Provide individuals specific notice that certain prescription drug information will be reported to a State prescription drug monitoring program and may be shared with programs of other States.
- Provide individuals with a right of access to their information that is maintained in a State prescription drug monitoring program and the right to contest the accuracy of the information.
- Limit the information provided under these programs to the minimum amount necessary to accomplish the intended purpose.
- Require recipients of information from prescription drug monitoring programs to only use the information for the purpose for which it was disclosed and prohibit them from further disclosing the information.
- Establish safeguards for verifying the accuracy of reported information.
- Establish security standards for maintaining and transmitting data.
- Require requests for inspection from most law enforcement agencies to be reviewed and approved by appropriate officials prior to disclosure.
- Require the de-identification of information provided for statistical, research, or educational purposes.
- Impose stringent civil and criminal penalties on the improper use and disclosure of prescription drug monitoring program data.

To the extent the Federal Government determines that it will directly operate prescription drug monitoring programs, these standards should also apply to the Federal program. The restrictions in the Privacy Act are insufficient.

Notice

Practitioners and/or dispensers of prescription drugs should be required to give individuals adequate notice that information related to prescriptions for certain classes of drugs will be reported to the State's prescription drug monitoring program. Individuals should be informed of who will have access to this information and the purposes for which they can use the information. Giving notice avoids any potential of "secret" databases. As a practical matter, adequate notice should also have a direct deterrent effect on "doctor shopping" because potential diverters will be made aware that their prescription drug information will be reviewed by the program and shared with other practitioners.

Most health care providers such as doctors and pharmacists already are required to give patients a notice of privacy practice under the HIPAA Privacy Rule. The HIPAA Privacy Rule, however, only requires a general notice of privacy practices that includes certain examples.⁵ To be an effective deterrent, notice under the prescription drug monitoring program would need to specifically advise consumers that if they have certain prescriptions filled, their prescription information will be reported to the State monitoring program. Thus, notice under the prescription drug monitoring program should be *in addition* to the notice required by the Federal Privacy Rule.

Access

Individuals should have the right to access and contest their identifiable data that is maintained in a prescription drug monitoring program. The right of access ensures that identifiable information is accurate and complete. Due to the sensitive nature of prescription drug information, it is particularly important that data collected be associated with the proper person.

Minimum Information

Only the minimum amount of information necessary to accomplish the intended purpose should be disclosed to recipients of information from prescription drug monitoring programs. This determination can be made at the policy level. The standard

⁵ See 45 C.F.R. §164.520.

should apply not only to information that is requested of the program but also to any disclosures that are made as a matter of routine.

Restrictions on Recipients of Information

Federal standards should require recipients of prescription drug monitoring program information to use the information only for the purpose for which it was disclosed. They should also prohibit recipients from sharing the information with others. Kentucky's prescription drug monitoring program incorporates these protections.

Integrity

The integrity of data in a prescription drug monitoring program is vital. Programs should be required to verify the accuracy of reported information. They should be required to either destroy old data or convert it to an anonymous form.

Security Standards

Maintaining a system of linked electronic databases with identifiable prescription drug information poses significant security risks. The information is sensitive and can potentially be improperly used against individuals. Because the information is identifiable and available in a concentrated format, it may also prove to be a tempting target both for hackers and for authorized personnel who may have improper motives to access the data. The information is a potential treasure trove for bitter ex-spouses, potential employers, and others.

Similar data has been compromised in the past. In the mid 1990's, a Florida Department of Health employee downloaded the names of over 4,000 AIDS cases from a county computer that stored mandatory reporting information on new AIDS cases and used the information for "dating" purposes. The names were also transmitted to two newspapers.⁶

Security measures can help prevent such loss and the unauthorized access, destruction, use, or disclosure of the data. Managerial measures include internal organizational measures that limit access to data and ensure that individuals with access utilize data for only authorized purposes. Such security standards should include role-based access and procedures for verifying that those outside the organization who request information have the authority to access the information. These measures should also include periodic audits to ensure that data is being accessed appropriately. Minimum standards should also be set for the technical protection of this sensitive data, including storing data on secure servers and encrypting information in transmission.

Serious consideration should be given to the manner in which information is collected and maintained in these programs. As discussed above, central data bases with names, addresses and prescription drug information are tempting targets for security breaches. Furthermore, the very idea of centralized data bases elicits strong reaction among many individuals. In the recent debate over whether Florida would establish a central data base for prescription drug monitoring, Rep. Rene Garcia (R-Hialeah) an opponent of the program stated, "My parents fled a Communist country because everything was being centralized."⁷

Some networks that share health information utilize other methods for linking their data. For example, the New England Health Electronic Data Interchange Network is well-known for its network which does not rely on a central database. Federal strategies to encourage the sharing of data between prescription drug monitoring programs should consider these alternative methods of exchanging data to decrease security risks.

Access by Law Enforcement

Prescription drug monitoring programs should not permit all law enforcement agencies unfettered access to collected data. Unfettered law enforcement access raises concerns from consumers and physicians that they will be improperly targeted for prosecution.⁸ Access should be limited to agencies acting within their official duties that are conducting bona fide criminal investigations or criminal prosecutions. Law enforcement requests to inspect prescription drug monitoring program data generally should be subject to review and approval by appropriate authorities prior to disclosure. In Massachusetts, for example, law enforcement agencies must

⁶Robert Trigaux, *AIDS List is Out*, St Petersburg Times 1A (Sept. 20, 1996); *Editorial: Protect HIV Patients*, Miami Herald Sec. L; page 2 (Oct. 13, 1996).

⁷David Royse, *Florida Legislature: State Would Keep List of Controlled Substance Users Under Bill-(AP)* (April 15, 2004) available at www.naplesnews.com/npdn/florida/article/0,2071,NPDN_14910_2809288,00.html.

⁸See GAO, *Prescription Drugs: State Monitoring Programs at 18*.

first direct their request for prescription drug monitoring program information to the Office for the Attorney General or the Massachusetts State Police Diversion Investigation Unit or the U.S. Drug Enforcement Administration for notification and approval.⁹

Access by Researchers

Some prescription drug monitoring programs make their data available for research or education purposes. To the extent that this information is made available, it should be furnished only in de-identified form.

Enforcement

Privacy protections can only be effective if there is real enforcement. State laws vary greatly in enforcement or penalty provisions. Some appear to provide only for minimal fines such as \$500.¹⁰

To ensure compliance with privacy standards, punishment should be public and severe.¹¹

Federal standards should provide for significant civil and criminal penalties for:

- Authorized personnel improperly obtaining, using or disclosing information from a prescription drug monitoring program.
- Recipient's improperly using or disclosing information that they obtained from a prescription drug monitoring program.
- Any person's improperly obtaining or using prescription drug monitoring program information.

States should, of course, remain free to provide for private rights of action.

III. Conclusion

Prescription drug monitoring programs appear to be an effective tool in reducing prescription drug diversion and abuse. Minimum privacy standards should be an essential component in any Federal programs to encourage the expansion and interconnectivity of these programs.

Senator SESSIONS. Congressman Whitfield, great to see you. I know you are having votes over at the House. We have heard from all the panelists now. We would be delighted if you would like to make your statement now, and maybe Ms. Pritts could move over, and just pull your chair up. We thank you for your leadership on this effort and for the progress that the legislation seems to be making in the House.

STATEMENT OF WHITFIELD, HON. ED, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF KENTUCKY

Congressman WHITFIELD. Mr. Chairman, thank you very much. I am quite excited about being here. I genuinely appreciate your holding this hearing, and I certainly want to thank Ms. Pritts for giving me her seat this afternoon.

[Laughter.]

Mr. Chairman, you are exactly right. This issue of prescription drug monitoring plans is a vitally important issue to our Nation. I think prescription drug abuse is a national issue and, as a matter of public health, one that Congress must address.

When we talk about prescription drug abuse, we are talking about individuals using controlled substances in a manner that is inconsistent with their prescribed use. Many people, all of us know, live with chronic pain or have pain as a direct result of a disease or injury. And in many cases, relief from that pain comes only from a controlled substance. Unfortunately, many people who are prescribed controlled substances to relieve pain, either on a long- or

⁹ 105 CMR 700.006.

¹⁰ See e.g., R.I. Gen. Laws 21-28-4.09.

¹¹ See Laurence M. Welsh, *Pink Slips Motivate Security Compliance*, searchsecurity.com (March 29, 2004) available at http://searchsecurity.techtarget.com/originalContent/0,289142,sid14_gci957013,00.html.

short-term basis, become addicted to them. The issue becomes how do we help prevent that abuse. And while there are a myriad of factors that contribute to the abuse of controlled substances, one important way we can combat this problem is encouraging State prescription drug monitoring programs.

Many States, as we have heard testified this afternoon, including my own State of Kentucky, have these monitoring programs, and I am not going to discuss the KASPER program because I know that Secretary Holsinger from Kentucky has already discussed our program. We think it is quite a successful program.

While KASPER has been effective in Kentucky, there is an inherent flaw in State prescription drug monitoring programs. They are only effective intrastate. Kentucky is bordered by seven States, and most of them do not have their own drug monitoring programs. For example, in my congressional district, we have 12 counties bordering with Tennessee, and Tennessee does not have a monitoring program. Therefore, a physician in Kentucky may receive a KASPER report indicating that the patient has never been prescribed a controlled substance in Kentucky, but they certainly do not have the access to what was prescribed next door in Tennessee. And that is one of the fatal flaws in our existing system.

In fact, the January 2004 Journal of the Kentucky Medical Association concluded an article on KASPER stating that the major problem with prescription drug information is that this information is not available nationwide, and prescriptions filled in out-of-State pharmacies to the KASPER system.

So I believe very strongly, Mr. Chairman, that the best way to address this issue is by requiring all States to establish prescription drug monitoring programs. And I have been working with my colleagues, Congressman Charlie Norwood of Georgia and Congressman Frank Pallone of New Jersey, on legislation mandating that all States enact a prescription drug monitoring program. And I am happy to say that this is one of those issues on which there is broad bipartisan support on the House side, and our bill, the National All Schedules Prescription Electronic Reporting Act, called NASPER, establishes a grant program housed at the Department of Health and Human Services which provides States with funding to establish and operate these programs. Our current draft requires States to cover Schedule II through IV controlled substances, allows practitioners and law enforcement officials access to the information, and, most important, provide for interstate operability. And, of course, we are quite cognizant of the importance of privacy and are still addressing that issue, have not resolved it completely at this time. But we did have a hearing on this, Mr. Chairman, and I specifically asked Secretary Tommy Thompson about creating such a program when he testified before the House Energy and Commerce Committee last spring, and he indicated that he supported a prescription drug monitoring program and specifically that he would support it housed at HHS.

With that, that concludes my testimony, Mr. Chairman. Once again, I want to thank you for your leadership, for your working with us, and I look forward to our continued cooperation as we try to solve this problem.

Senator SESSIONS. Well, thank you for that excellent statement and summary of the situation.

Let me ask you, Congressman Whitfield, are you finding growing support for this in the House? I know it is always dangerous to predict anything, but do you feel pretty good about how the House is considering this legislation now?

Congressman WHITFIELD. Well, I do, Mr. Chairman. We have worked very closely on both sides of the aisle in the Energy and Commerce Committee with staff and with members, and things are really coming together right now. Right now we have a hearing scheduled—not a hearing, we actually have a markup scheduled next Thursday with the full committee, and we expect—recognizing what you said that you can never state with 100-percent certainty, but we feel that the bill will be reported out of our committee at the end of next week.

Senator SESSIONS. I think that is a compliment to you and the leadership that you have given to it, and maybe to the merits of the issue. The growing States that are doing it, more and more States are undertaking this, is a good indication something is working, don't you think?

Congressman WHITFIELD. Absolutely, and it is my understanding that the total number of States that either have a program or are working to establish programs right now is somewhere in the neighborhood of 31. So there is momentum out there. There is certainly a need. And as I said, I look forward to working with you and other Members of the Senate to help address this problem.

Senator SESSIONS. Well, thank you. I would be delighted for you to stay. You can join me here or stay there, and I have some questions for the other members of the panel, too. And if you have any final comments, we would welcome them.

Congressman WHITFIELD. Well, thank you very much, Mr. Chairman. I would like to stay and hear a few questions and answers, and then I am going to leave. We have a product in Kentucky called tobacco, and we have a little hearing on that at 3 o'clock, and so I need to get over there for that. I know this is a health hearing, but this relates to farmers. So thank you.

Senator SESSIONS. I understand. Very good.

[The prepared statement of Congressman Whitfield follows:]

PREPARED STATEMENT OF CONGRESSMAN ED WHITFIELD

Thank you Mr. Chairman for the opportunity to testify before the committee on an issue that is very important. Prescription drug abuse is a national issue and, as a matter of public health, one Congress needs to address. President Bush has made a commitment to curbing prescription drug abuse through the Office of National Drug Control Policy and I know we will make every effort to work with him on this issue.

When we talk about prescription drug abuse, we're talking about individuals who are using controlled substances in a manner that is inconsistent with their prescribed use. The Federal Government exercises its authority in this area through the Controlled Substances Act of 1970. The Act classified drugs into five schedules based mostly on their potential for abuse. Although Schedule I drugs, such as heroin, are not legally available, Schedule II

through V drugs are. However, the production and distribution of these drugs, such as OxyContin, are regulated by the Drug Enforcement Administration.

I recognize that many people live with chronic pain or have pain as a direct result of a disease, such as cancer, and in many cases relief from their pain comes only from a controlled substance. It is important that those individuals continue to have access to such drugs. Unfortunately, some people who are prescribed controlled substances to relieve pain, either on a long or short term basis, become addicted to them. And many individuals who have not been prescribed these drugs illegally obtain them as an alternative to other drugs.

We are all familiar with the problem of prescription drug abuse and the millions of Americans who use these drugs for non-medical purposes. The issue becomes, how do we help prevent the abuse? While there are certainly a myriad of factors that contribute to the abuse of controlled substances, I believe one important way we can combat this problem is through enhancing State prescription drug monitoring programs (PDMPs).

Many States, including my own State of Kentucky, have PDMPs. Our system, known as the Kentucky All Schedules Prescription Electronic Reporting (KASPER) program, is effective. I know Secretary Holsinger will discuss KASPER in greater detail, but to summarize, KASPER requires all prescription drug dispensers in Kentucky to electronically report information on Schedule II through V controlled substances to a database operated by the State. The database contains information on individuals who have been prescribed any of those scheduled drugs, including the prescribing physician, and the pharmacy where the prescription was filled.

In addition, law enforcement authorities have access to the database under certain circumstances. This partnership of physicians and law enforcement strikes the right balance of treating those who have addiction problems and prosecuting those who are breaking the law.

Physicians in Kentucky use KASPER to obtain information on their patients to determine if they have previously been prescribed one of these scheduled drugs. This is an invaluable tool for doctors in determining the best treatment for their patients. If by using KASPER a doctor discovers that a patient complaining of pain was recently prescribed OxyContin by another physician, and the patient failed to disclose that, it gives the doctor an indication that their patient may have an addiction problem.

While KASPER has been effective in Kentucky, there is an inherent flaw in State prescription drug monitoring programs: they are only effective intrastate. Kentucky is bordered by seven States and (Tennessee, Missouri, Illinois, Indiana, Ohio, West Virginia, and Virginia) most do not have their own drug monitoring systems. For example, I have 12 counties that share the border with Tennessee.

Tennessee does not have a PDMP. Therefore, a physician in Kentucky may receive a KASPER report indicating that their patient has never been prescribed a controlled substance in Kentucky, but has no way of knowing if that individual has received and filled a prescription in Tennessee.

Because individuals seeking to obtain fraudulent prescriptions for controlled substances is a national problem, I believe drug monitoring programs must also be national. A physician in Kentucky, or any other State, should be able to receive a report on a patient that will tell them not only if that patient was prescribed a controlled substance in their own State, but in any State. The January 2004 *Journal of the Kentucky Medical Association* concluded in an article on KASPER "Another problem with prescription drug information is that this information is not available nationwide. Prescriptions filled in out-of-State pharmacies are not reported to the KASPER system. Patients who tend to abuse prescription drugs may be fully aware of the limitations of the KASPER system and seek to fill prescriptions outside the Commonwealth."

I believe the best way to address this issue is by requiring all States to establish prescription drug monitoring programs. I have been working with my colleagues, Congressman Charlie Norwood and Congressman Frank Pallone, on legislation mandating all States enact a PDMP. Our bill, the National All Schedules Prescription Electronic Reporting (NASPER) Act establishes a grant program housed at the Department of Health and Human Services which provides States with funding to establish and operate PDMPs. Our current draft requires States to cover schedule II-IV controlled substances, allow practitioners and law enforcement officials access to the information, and most important, provide for interstate operability. I asked Secretary Tommy Thompson about creating such a program when he testified before the House Energy and Commerce Committee last spring and he indicated his support for a national PDMP housed at HHS.

This is a delicate issue as it involves physician prescribing practices and we must be certain that our efforts are targeted at preventing the abuse while ensuring that all Americans suffering from pain continue to have access to needed medications. The last thing we want to do is scare doctors and patients and create a situation where physicians are under treating pain for fear of being arrested and patients are under reporting pain out of the same fear. Existing PDMPs operate on that principle by involving all stake holders such as State medical and pharmacy boards, law enforcement, and public health officials. I believe a system focusing on only one side of the equation is not beneficial and yields no long term benefits. Prevention is the goal and we must keep in mind that doctors are the main source of these drugs. Above all else, our efforts should be focused on preserving the integrity of the doctor-patient relationship.

The Federal Government has a clearly established role in this area, and any efforts to further enhance the monitoring and distribution of controlled substances should have a Federal component. NASPER would be an invaluable tool, especially for physicians, in our efforts to prevent prescription drug abuse.

Senator SESSIONS. Dr. Holsinger, let me ask you just a few questions first. Kentucky, as I understand it, thought you had a fairly serious problem with prescription drug abuse before this program was initiated, and if that is true, do you feel that there has been any reduction in the size or scope of that problem as a result of your program?

Dr. HOLSINGER. Well, I think that we have been able to see certainly a heightened awareness of the issue, and I think that we probably have been able to see a reduction. It is hard to quantify because the drug of choice tends to change depending on the enforcement around any one particular pharmaceutical agent. So it appears that in Kentucky, where OxyContin was the major drug of choice for abuse, that is now slipping and it looks like it is going to slide into second or third place. So the problem is that as you maintain control in one sphere, it is very easy for another drug to become the drug of choice.

Senator SESSIONS. I remember being active in an effort to deal with the prescription drug problem in Mobile when I was a prosecutor, and, in fact, we made tremendous progress. Talwin mixed with another drug was as addictive almost as heroin, and we virtually eliminated that. That was sort of a remarkable achievement to me. It made me come to believe that this is a winnable war. It is hard to stop marijuana and cocaine that comes in under the table from every area around the world and just filters through. But prescription drugs come through pharmacies, through doctor prescriptions. It is not that easy, and we have laws in place that were designed to stop the abuse.

We are really not altering, as I understand it, Ms. Green, any of the fundamental principles that we have already had. We are just updating them with technology so they more effectively work to stop the problem. Would you agree with that?

Ms. GREEN. I would, Senator. One of the things we stress is that this is a particular database mechanism. It is a way of expediting the collection and analysis of the information precisely so the system can be used as a means of early identification.

So the system itself does not actually change any particular rules, laws, or regulations, that exist in a State. It simply expedites the ability of all the officials in the State and prescribers to be able to identify as early as possible a problem and then address it as early as possible.

Senator SESSIONS. We do not need to be prosecuting people if we can avoid it. There is a certain small number of just utterly unscrupulous people that know how to forge prescriptions or get drugs and sell them for a nice profit, as Dr. Varley indicated. But there are a number of people who become addicted and get driven to have that drug again and again and again. And they lie to physicians. They go around to multiple physicians. And that is, I think, Dr. Varley, something that you mentioned.

Let me ask you, Dr. Holsinger said at first physicians were somewhat skeptical of this program in Kentucky. I know in other times in the Senate we have had pain physicians express some concern about regulation because they were afraid it would keep them from perhaps prescribing drugs to people who needed pain relief. But your national group represents over half the pain physicians in America who actually—these are the people prescribing these painkillers on a regular basis. You strongly support this legislation. In fact, you are pushing it. Do you think that physicians nationwide are coming around to seeing the value of this kind of control?

Dr. VARLEY. Yes, I believe that this is an important part of providing excellent care to our patients. We have to be able to dif-

ferentiate between the legitimate and the illegitimate patients. And we can try to do this with our history-taking skills or doing due diligence in determining that there is an accurate diagnosis, that the patient is actually exhibiting pain behaviors. That is all a part of the practice of medicine.

However, we have no way of knowing whether that patient goes to another doctor across the street or across the State line to get other types of medications. So I think that this will enable us to practice a higher quality of medicine to make sure that patients who need specific drugs, whether they are narcotics or other psychological medications, and not have to worry that we are going to be putting that patient at risk because of multiple medications or putting our children at risk because the drugs are being sold in the schoolyard.

So I think that the physicians that I know, the bona fide pain physicians who are working for the best interests of our patients, strongly support this type of legislation.

Dr. HOLSINGER. Senator, I think it is fair to say that in Kentucky, physicians today are very accepting of this and recognize it as a major tool, as Dr. Varley has said, in their practice in order to provide quality care to their patients. And I think that is one of the key reasons why 85 percent of the requests to date have come from physicians. They see the usefulness of this information in the care of their patients, and I think that is a real plus as we move forward into the future.

Senator SESSIONS. So 85 percent of the inquiries to determine whether or not someone has multiple prescriptions come from physicians who are concerned about their patients. Is that basically it?

Dr. HOLSINGER. That is correct. It is interesting, in our situation only 4 percent come from pharmacists, but the pharmacists are a key part of this; 8 percent from law enforcement; 2 percent from the licensure board. We have had none by court order or subpoena at this point in time, so it has been a very effective tool for physicians.

Senator SESSIONS. Well, I think that does go to the point that this is a patient treatment issue, a physician-patient treatment issue. In other words, Dr. Varley, I have heard physicians tell me, I have heard pharmacists tell me, I have heard dentists tell me that people come by and they can pretty well spot them, and they are script-getters. They come in and complain about pain, and they are dubious immediately about it. Some tell me, "I just will not do it. If I have an uneasy feeling, I will not write it." But that is pretty embarrassing for a physician, is it not, a little bit difficult for the physician who has no real proof of the problem? Does this give a physician better information to make a better decision if he has some doubt about the patient that is asking for pain relief?

Dr. VARLEY. I think—and I brought up in my presentation—that the timeliness of this information—

Senator SESSIONS. You did. You used "real time." And what do you mean by that?

Dr. VARLEY [CONTINUING]. Real time so that if a patient is in your office, that within the time, the 20 or 30 minutes that the patient is physically present in your office, that you can get useful information back. What we are currently doing is routine or random

urine drug screens, and what I not uncommonly have to do, unfortunately, is when I find a patient who does not have the drug in their urine that I am prescribing, it generally means that they are either giving it to somebody or they are selling it on the street. So that is currently—and that is a reactive way of doing it. In other words, I already prescribed the medication. They are already diverting it on the street. And then I find out that this is going on.

So if I have a tool that will enable me to preemptively not write that prescription, then it is better for the patient, better for the people that would be exposed to that drug.

Senator SESSIONS. And if you saw a large number of prescriptions that that patient had obtained and you knew that they were abusing the prescription drug, would you refer them for treatment? Would you counsel them?

Dr. VARLEY. I would definitely counsel the patient. We have some patients who openly admit that they have a problem. In my practice, I have a psychologist who works with me, and when we identify patients with those problems, we try to direct them either to a psychologist or an addiction specialist to try to get them help with their problem.

Senator SESSIONS. Dr. Varley, the—well, I had a very good question. It got out of my mind, and I will go to the next one to Ms. Green. You said there was a study that was being undertaken now that may give us some good information about how effective this is. Would it give us any information about any cost savings in terms of Medicaid and Medicare or private insurance carriers?

Ms. GREEN. That is correct, Senator. The National Institute of Justice has contracted with a company to actually design an evaluation which could then be applied to the existing State programs to actually determine the cost-effectiveness and the costs and benefits looking at indicators such as Medicaid fraud costs, decreases in Medicaid fraud, even insurance fraud, what has happened to that, decrease in investigation time, to determine the true effectiveness of the programs, and also to use the information as a way to constantly improve the effectiveness of the programs.

Senator SESSIONS. I am a big believer that the National Institute of Justice should help in these areas, and I will look forward to supporting their efforts, because one of the best things the National Institute of Justice and the Department of Justice can do to deal with drug and crime problems in America is provide good research information to the States. The States can oftentimes devise their own programs, but they are not often able to spend the money to do a major study. So I am glad to see that is being done. Do you have any idea when it might be completed?

Ms. GREEN. I know that the evaluation design itself is supposed to be completed by the end of the year. After that, they will then begin the evaluation process, which to my understanding this could occur anywhere over the next 9 to 12 months. But that has not been decided definitively yet.

Senator SESSIONS. Ms. Pritts, the question of a database a legitimate one. If it is easy for a physician to get information or if it is easy for law enforcement or a pharmacist, or the licensure board to get information, it could also be easier to disseminate that information.

First, let me ask Ms. Green and Dr. Holsinger, are you aware of any abuses of systems that you are aware of around the country or in your State?

Dr. HOLSINGER. We are not in Kentucky, Senator. We have, we think, pretty stringent sanctions on the inappropriate or illegal use of this kind of information. As I said, to use it illegally is a Class D felony. That is 1 to 5 years in prison. It is a real effort to make sure that we do use it only appropriately. And we have chosen to build into our system the HIPAA privacy pieces to it in an effort to be able to make sure that we are making at least—having a system that is HIPAA-compliant.

Senator SESSIONS. And that had not made—has there been any problem in the operation of the system?

Dr. HOLSINGER. It has not at this point in time. We have one outstanding issue, as we are finalizing the development of our electronic system, that will take us to 15-minute turnaround time for physicians. And we are waiting for an opinion from our general counsel's office as to whether or not we have to treat law enforcement as a business partner under HIPAA regulations. If we have to treat them as a business partner under HIPAA regulations as we apply them in this system, that will cause some constraints on our law enforcement efforts, I think. But we do not have an answer to that question at this time yet.

Ms. GREEN. Senator, none of the existing operating programs, including those that have been operating since 1939, have had any successful claims based on inappropriate disclosure of information or inappropriate use of the information by the operating system.

Senator SESSIONS. Now, Ms. Pritts, right now pharmacists, and, overwhelmingly, most pharmacists, have a computerized system, bar code, or whatever that clocks in the—I guess they clock in and inventory their drugs when they come in, and they are inventoried as they go out at the checkout counter or the cash register. That is available to, I guess, abuse of anybody who has access to that system in that pharmacy. This would create access to all of that information at one central State source that could be accessed by doctors throughout the State.

So my understanding is that your concern is it would be easier for a person to explore the system if they could penetrate that if you have a statewide system. Is that your concern?

Ms. PRITTS. Well, it is the size—there are a number of issues here. One is the size of the database. As you include more people, it becomes more tempting for people to hack into. Information is very valuable, especially in today's economy. And there was a recent situation up in Canada where somebody stole a Canadian online pharmacy, their database, and then they tried to sell it to people at a profit.

So, similarly, when you have a lot of information in one place, particularly if it is information that people might be embarrassed about or would prefer not to have made public, it becomes almost like candy in a candy store for some people who would like to either hack into that information just for fun or because there is somebody that they might have a vendetta against and they think it might be in there, people who are just on fishing expeditions, too. So the bigger it is, kind of the more attractive it can be.

Dr. Holsinger was talking about the privacy protections they have in place in Kentucky, which sound like they are quite stringent, and there are a number of other States that also have those types of protections. And it would be good if everybody had the same level of protection.

We had the same situation just with regular medical information prior to HIPAA. There was a lot of it that was in paper format. People recognized as you move it into an electronic format, you are dealing with a different kind of animal. If you want a copy of the data, you don't have to xerox thousands of pieces of little prescription pads. You just hit a mouse button, and you have it.

Senator SESSIONS. It is very, very difficult in a State system that is not automated to get information. For example, cases I have seen and investigated, investigators may have to go find paper records at Pharmacy A and go around and check virtually every pharmacy in town because they do not know which one the abuser used. So it is almost—that is one reason it is so intimidating, that very seldom do we do that, so you have got to balance the danger of a concentrated thing to have some privacy dangers there against basically the workability of the entire system that we have created. Would you agree that is what we are wrestling with?

Ms. PRITTS. I do agree that balancing is a very difficult act, and there are systems in place where they do this quite effectively on a fairly real-time basis with doctors where they do not use a central database. And I think those are at least worth investigating as an alternative.

People are very—the American public is—there is a big section of the American public that is very concerned about the development, the continued development of these large databases with a lot of identifiable information in them. There are a number of people who see the black helicopters circling every time you mention government, the government getting involved in this, and particularly with the Federal Government getting involved in it. I think that those present real road blocks.

Senator SESSIONS. I do not think there is any doubt that people are worried. I will say this, though. I do not find a lot of people coming up to me that say on the HIPAA or other regulations that this hospital violated my privacy or this insurance—in theory, they are concerned about the possibility, but I am not seeing a great uproar to me about specific instances of privacy violation.

Dr. Varley, you said something interesting that you often—or how often do you prescribe a urine test on your patients? And why do you do that?

Dr. VARLEY. I feel like I am Detective Colombo sometimes. We have suspicions. Part of it comes from the assessment of the patient when they come in. What are their subjective complaints? How severe and where is there pain? Does it make physiologic sense? When we do a physical examination, does it correlate with their complaints? And then there is that unwritten, unspoken feeling that you sometimes get, you know, you are suspicious.

We do both routine and random drug screens on patients. Certainly the drug of choice, as I said in my presentation, appears to have been OxyContin, but other drugs—certainly Dilaudid was

mentioned and hydrocodone and methadone. All of those drugs have the potential for abuse.

So I basically do the urine screens as part of what I consider the good practice of medicine to identify those patients who are abusing my services and the health care system and diverting the medications.

Senator SESSIONS. What do you find when you do the—what is a concern? What do you often find when you do one of those screens?

Dr. VARLEY. Being an Attorney General in the past, you probably realize how can you tell when a drug addict is lying? Their lips are moving. They will deny—you know, you show them the—I show them the report. I do not tell them. I show them the report. And they will deny, and they will come up with all sorts of different explanations for why the drug is not in their urine. And I have seen probably most of the stories or heard most of the stories about why it is not in there.

Senator SESSIONS. But that helps you—you do not call the police and say come arrest them at that point?

Dr. VARLEY. Personally, I feel that would be a conflict of interest in my physician-patient relationship.

Senator SESSIONS. Your goal is to try to stop the bad behavior and help your patient. Is that correct?

Dr. VARLEY. No, in my narcotics agreement that I have with my patients, they give me the right, once I prescribe medications, that should a law enforcement officer come and ask to see their medication records—now that does not mean that they get access to the full medical record but just their medication records—then they give me the right to give that information to that law enforcement officer. So we provide that information if they are under investigation from probable cause out in the community.

Senator SESSIONS. And the association, ASIPP, that you belong to believes that in your experience of dealing on a daily basis with people suffering from pain and understanding and seeing the reality of the addiction problem in America, that this kind of system that they are doing in Kentucky and other States is humane and beneficial and helpful in treating people and helping people to avoid addiction problems.

Dr. VARLEY. I think that there may be three different types of patients that we are dealing with here: Patients who have legitimate pain conditions that are being appropriately treated, let's not try to discourage physicians from appropriately treating those. We have other patients who have an addiction problem; their problem is not pain, their problem is addiction. So to practice good medicine we have to get them into a program that will address their addiction. And then there is a third group and, quite frankly, they are outright criminals. They are obtaining drugs fraudulently and making a buck off of other people's misery.

Senator SESSIONS. Well, they do need to be reported to the police. I think you are correct.

You mentioned young people. After I ceased being a prosecutor, not long before I became a Senator, I got asked to represent a young man who had been president of his high school senior class, had been injured in sports and had knee pain, and was getting

scripts passed all over town, and it said one refill, he would raise it to seven, and things like that. It was really sad, very sad.

Do you think that young people might be reluctant to try cocaine or heroin, but be less afraid of prescription drugs and get in trouble with them more than we would suspect?

Dr. VARLEY. I think that there is a tendency to that. I think it is a matter of availability, it is a matter of education, and maybe physicians, we should take a more active role in our school system to educate our young people about the dangers. And, unfortunately, I have a report similar to the one you told us here 2 weeks ago. I was talking to my wife just before we came into the committee, and she called to tell us that an acquaintance of one of my other daughters, who is attending Auburn University, died of a methadone overdose. And that is something that just happened yesterday. And so, I mean, this is a real problem. It is affecting people in all avenues of society, and particularly—this young person had a future ahead of them. They would have been very productive. And, unfortunately, they got caught up in this illicit prescription drug use and died in the process.

So I think we do have to educate. We have to decrease the demand for these drugs as well as to decrease the availability of them.

Senator SESSIONS. Would any of you have anything further to add? Dr. Holsinger?

Dr. HOLSINGER. Thank you, Senator. I was just going to add that an individual who ends up abusing prescription drugs has to start some time. They do not start at a full-fledged abuse situation. A system like ours, electronically operated with 15-minute turnaround time for a physician, in other words, real time, an opportunity to know what is going on, I believe will give us the opportunity to have early intervention as well and be able to identify individuals who are initially starting the types of behavior that indicate that they are abusing these kinds of substances and, therefore, have an opportunity for much earlier intervention than having to deal with the backlog of individuals that we are identifying now that have had longstanding issues.

Senator SESSIONS. Well, that is exactly my thinking, because we need to stop this before they become seriously addicted. You know, you can get habituated to a drug, but if you can find it early enough, perhaps they are not as addicted and it is so hard to quit. I dealt with a witness in a case, and he just could not stop—could not—I mean, he would go into a frenzy to have another fix of drugs. And, also, they can get arrested. Also, if they are not stopped early, then they have to go through a long and expensive treatment program. Families can break up. People can lose their jobs. They can abuse their spouses. Children get abused with people who are addicted to drugs. Or they use their money up. They become financially unable to pay their bills and take care of their families.

So I think that there is a human need out there that is very significant. It strikes me that since we are keeping all these records anyway, everybody has to keep them—the pharmacist, the doctor—and DEA and other places can review them and all of that. We might as well keep them in a way that the physician can have ac-

cess to them and maybe intervene and stop this kind of problem in the future.

Any other comments? Ms. Green?

Ms. GREEN. Yes, Senator. I would just like to build on the conversation by suggesting that in order for a PMP to be as effective as possible in intervening at an earlier stage of someone's addiction, States will need to be willing to dedicate sufficient treatment resources so that once these people are identified as needing treatment, there is somewhere to send them, meaning an appropriate treatment program.

Senator SESSIONS. I tend to agree with that. There are a lot of avenues to deal with addiction absent long-term, highly expensive institutional treatment. We are trying to get some studies done by the National Institute of Justice on some of those programs, how well they work and what is the best to spend limited resources on. But obviously the best thing is not to be addicted to begin with, stop it to begin with.

Anything else?

[No response.]

Senator SESSIONS. Thank you for your comments and your remarks. One thing, if we do have sufficient funding, Ms. Pritts, perhaps we will be better able to meet some of the ideas and suggestions you have to make the system better. I think a number of the suggestions you made on privacy issues could be adopted with not a lot of expense and might be very practical as the State goes forward. So we thank you for sharing that with us.

We will leave the record open. I know Senator Dodd had requested to be able to submit a statement. We will keep the record open until close of business tomorrow.

[The prepared statement of Senator Dodd follows:]

PREPARED STATEMENT OF SENATOR CHRISTOPHER J. DODD

Mr. Chairman, I want to thank you for holding a hearing on the issue of abuse and diversion of prescription drugs. I am hopeful that this hearing will shed some light on the severity of this problem in our country and provide a forum for discussion about solutions to the problem, including the establishment of a Federal Prescription Monitoring Program (PMP).

More than six million Americans use prescription drugs for non-medical purposes. The majority of prescription drug abuse occurs with pain relievers. While these drugs are absolutely critical for the millions of Americans suffering from chronic pain, if used improperly they can lead to addiction.

The potential for abuse of these drugs presents a serious challenge. We certainly do not want to prevent physicians from prescribing them to patients. Access to pain relief improves the quality of life for millions of Americans, many suffering from serious and debilitating illnesses. At the same time, abuse and diversion of these drugs ruins lives, destroys families, and results in thousands of deaths each year. Prescription drug abuse is also becoming a disturbing trend among youth. Among 18–25 year olds, only marijuana is abused more frequently. Just over a week ago, an 18-year-old in New Fairfield, Connecticut died after overdosing on a prescription pain medication.

Much of the testimony at today's hearing will focus on the use of PMPs to reduce prescription drug abuse. It is my belief that monitoring programs have the potential to be an enormously valuable tool in our fight to reduce prescription drug abuse, and I applaud this committee for taking a close look at this approach.

At the same time, any successful program to combat prescription drug abuse must keep the following principles in mind. First, it is critical that the confidentiality and privacy of patients are protected. We must not create a system where PMPs are used to target patients for prosecution. Those suffering from chronic pain should know that they can seek relief from their suffering without jeopardizing their right to privacy. Along the same lines, we must ensure that physicians can continue to appropriately prescribe these medications without undue fear that they will run afoul of law enforcement. PMPs should be used to help physicians identify patients in need of help and direct them to the appropriate services.

We also must make sure that the information in PMPs is used appropriately. Of course, we must continue to support law enforcement efforts to fight prescription drug abuse. Where laws are being broken and drugs are being diverted by dealers for sale on the streets, we should provide law enforcement with the tools necessary to prosecute criminals. However, we must do so in a way that respects the civil liberties that are the cornerstone of our democracy. While PMPs can be helpful in bringing criminals to justice, access to this sensitive information must be carefully controlled lest it is abused.

Once again Mr. Chairman, I appreciate your willingness to shed light on this important issue, and I thank all of the witnesses for being here today. I look forward to working with my colleagues to address prescription drug abuse and diversion, while ensuring that patients can continue to benefit from necessary medications without risking their privacy.

Senator SESSIONS. If there are no other comments, we will be adjourned, and thank you so much for your excellent testimony.

[Additional material follows.]

ADDITIONAL MATERIAL

STATEMENT OF DAVID KLOTH, M.D.

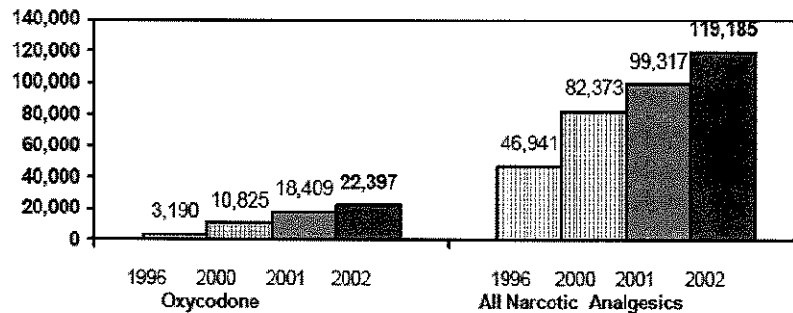
It is my pleasure to present the committee information on what has become an extremely serious health problem in the United States. Prescription medication substance abuse and diversion has reached epidemic proportions in this country. It is affecting many aspects of our society, but perhaps most concerning, is the widespread availability of these powerful and legal medications to children and young adults. Each and every day another young life is claimed from drug overdose caused by readily available and seemingly legal medications. Millions of American adults are addicted to or inappropriately using schedule II, III, and IV controlled substances.

My name is David Kloth, I am an actively practicing board certified pain physician. I am the Executive Vice President of the American Society of Interventional Pain Physicians (ASIPP), the President of the Connecticut Pain Society, and the Founder, Medical Director and President of Connecticut Pain Care. Each and every day I treat patients suffering from a multitude of different pain conditions, often using chronic narcotic medications to help control these symptoms. As an interventional pain physician, I have many different options available to help treat pain. My initial approach and treatment goal is to control an individual's pain with targeted (fluoroscopically or X-ray guided) injections, thereby treating the pain at its source and hopefully eliminating the "pain generator." Even with such treatment, many patients still require pain-relieving medications. Unfortunately, some patients acquire and/or use prescription medications for non-medical purposes. Substance abuse may lead to a given patient's own demise; even worse, when diversion of medications to our streets occurs, it can cause tragic consequences to the innocent and unknowing.

PRESCRIPTION MEDICATION ABUSE TODAY

An estimated 4.4 million Americans used prescription pain relieving medications for non-medical purposes in 2002. This has resulted in hundreds of thousands of emergency room visits each year. The Drug Abuse and Warning Network (DAWN), in a November 2003 report, showed a 210 percent increase in emergency department visits from 1994–2002 for psychotherapeutic drugs, including opioids (narcotics) and benzodiazepines (sedatives).

Estimated number of emergency department mentions for total coterminous United States from 1996 to 2003 increased substantially.

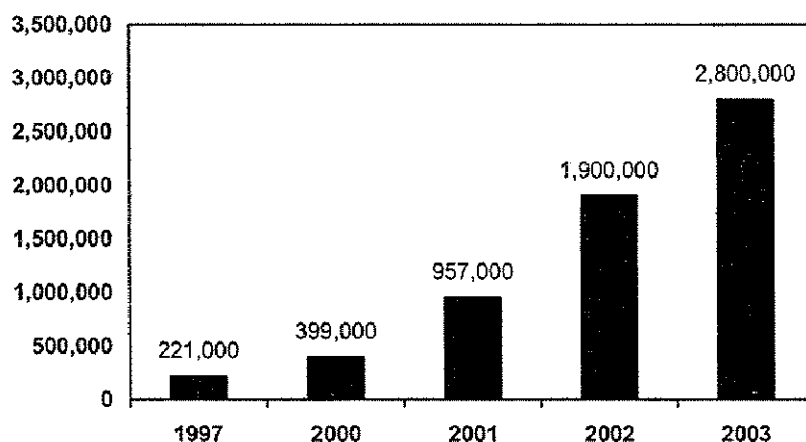


Estimated number of Hydrocodone and Oxycodone Emergency Department (DAWN ED) mentions for total coterminous United States: 1996–2002

Drug diversion and abuse is associated with increased crime rates and has a destructive effect on the family, including our children. Neonatal units are seeing increasing numbers of "Oxy-babies." There are thousands of fatalities in the United States each year from prescription medication overdose. The economic cost to society of treating these individuals has been estimated in the billions of dollars. The indirect costs through lost productivity, associated criminal activity, accidents, rehabilitation, and family destruction (to name just a few), is difficult to measure. One study by the Office of Management and Budget, estimated costs associated with drug abuse in the United States at \$300 billion a year, this included the expense

of government anti-drug programs and the costs of crime, healthcare, accidents, and lost productivity.

During 2002 a questionnaire (from *Monitoring the Future* Study) regarding Oxycontin usage revealed, 1.3 percent of eighth graders, 3.0 percent of tenth graders, and 4.0 percent of twelfth graders reported using Oxycontin for non-medical reasons. In 2003, this increased to 1.7 percent, 3.6 percent, and 4.5 percent respectively. The problem is growing. It is estimated that over 32 million Americans have used pain-relieving medications for non-medical purposes-lifetime usage (from National Survey on Drug Use and Health-HHS). Non-medical use of Oxycontin has grown from 1.9 million in 2002 to 2.8 million in 2003, and in 2004 will approach 4 million. Oxycontin's potency and its handy distribution network—local pharmacies and the internet—have made it more insidious and difficult to control than any other drug. A 1997 Household survey on Drug Abuse revealed that the non-medical use of prescription drugs exceeded all illicit substances except for marijuana and hashish. In the age group of 18–25 year old the incidence of marijuana usage is estimated at 17.3 percent and the non-medical use of prescription medicines is 5.4 percent.



Non-Medical use of OxyContin

PRIOR HELP COMMITTEE HEARINGS

In the past, the Senate HELP Committee has had hearings on Oxycontin, prescription drug abuse and diversion. This issue is not new to our government. NASPER is a solution to one component of this problem, "doctor shopping." NIDA (National Institute on Drug Abuse) in prior hearings has informed the committee of the seriousness of this problem and has directed significant attention to this problem by encouraging research and program development for more effective behavioral and pharmacological treatments of this problem. Abuse of prescription drugs now ranks third in this country behind only alcohol and marijuana.

THE LEGITIMATE TREATMENT OF PAIN

When used properly, as legitimately prescribed by the physician, these medications are safe, effective, and medically indicated. Controlled prescription drugs play a significant role in the proper management of chronic pain, anxiety, depression, insomnia, and muscle spasm. The proper and adequate control of pain has improved the lives of millions of Americans with debilitating and painful conditions. Prescription medications are essential to high quality cancer pain management. However, when prescription controlled substances are abused, misused, or diverted they can become dangerous and even lethal. These types of inappropriate use shed a cloud over this extremely important treatment modality, thus making it more difficult for those who can truly benefit from this worthwhile approach. The pain community has spent years trying to convince physicians, the public, law enforcement and legislators about the need to improve access to this treatment and over the last 10 years

we have seen the barriers practically disappear. Today, as many as 90 percent of the patients seen in a pain management clinic receive narcotic pain medications (either as sole therapy or in addition to other treatments) for the treatment of their chronic pain. With this increased access have unfortunately come new problems as we have seen with the rampant spread of these medications on the streets of America.

NON-MEDICAL USE OF PRESCRIPTION MEDICATIONS

We are all familiar with the recent Oxycontin crisis, but this is only one of the medications with which we see diversion and abuse. In fact, hydrocodone (also known as Vicoden or Lortab) and Percocet are more widely abused and easily obtained on our streets. Millions of patients are addicted to and misusing these medications to the detriment of their own health. These individuals are becoming addicted to very powerful medications that can be legally obtained in any pharmacy. When used for non-medical purposes, these medications are as dangerous as heroin, cocaine, ecstasy, and other illicit drugs. Because of their ready availability, many addicts have converted to using prescription medications from typical street drugs. This problem and source of drugs, has become as important, as the illicit drugs that come across our borders.

The non-medical use of prescription drugs has blossomed into one of the most serious health problems in this country. The wide spread availability of these highly addictive medications through illegal diversion and theft has resulted in a national health care epidemic. Since these medications can be obtained through legal channels, it has presented an extreme challenge to law enforcement in this country. Recent statistics show that the United States consumes 80 percent of all legal opioids produced worldwide. This is in large part due to the high quality of our medical system and the emphasis that is placed in this country on adequately and properly treating pain. This availability also demonstrates why these medications have replaced heroin and other illicit drugs as popular drugs on our streets. With this increased availability comes increased responsibility and, hence, the need for H.R. 3015 or NASPER (National All Schedule Prescription Electronic Reporting Act).

DRUG DIVERSION

Prescription drug diversion can occur many ways but by far the most common form of diversion in this country occurs via what we call "doctor shopping." Those who seek to abuse or misuse medications for their own purpose also use this approach. Doctor shopping refers to the activity of obtaining medications from more than one physician at the same time, as demonstrated in the recent case of Rush Limbaugh. This source of diversion would be readily reduced, if not eliminated, by a program such as NASPER. Currently, it is impossible in most States for physicians to prevent this activity due to an inability to obtain the necessary information. As the borders have been tightened, drug dealers have discovered new ways to obtain drug supplies to push on our innocent youth. Prescription medication abuse and diversion is a serious problem because of the powerful nature of these pure, and potentially addictive, medications. It is these legal prescription medications that are now finding their way to the streets of America. Current DEA estimates suggest that at least 4.7 million people are using prescription medications illegally in this country. An estimated 994,000 Americans received treatment for prescription drug abuse in 2002.

THE DARK SIDE

Last week in my area, an 18 year old and recent New Fairfield, CT high school graduate, died, from what his sisters and friends confirmed was an Oxycontin overdose. The newspapers described him as "a man of great compassion . . . he was a happy boy. He had a lot of friends and he wouldn't hurt anyone." To his friends and family, this is an incredible loss; "I'm going to hurt till the day I die" said his father. Let this example be a message to us all, a wake-up call that it is within our power, the ability to decrease the availability of these medications on the street. If we can prevent this from happening to one other individual, what is this worth? To hundreds? To thousands? What if this was your child? While NASPER will not completely eliminate the street availability of all prescription controlled substances, it will go a long way in this regard. If we can prevent our children from trying these powerful medications, by eliminating or at least markedly restricting their street availability, we can prevent addiction and the horrible and possibly fatal consequences. The State of Connecticut Medical Examiners office deals with an estimated 10-15 new overdose deaths/week; many of these are related to prescription medications (estimated at close to 1,000 in the last several years).

THE SUPPLIER

Four years ago, I found that one of my patients was photocopying and forging my prescriptions. He had obtained over 4,000 Oxycontin tabs from six different pharmacies in a 5-month period (this is what we could track down by randomly calling pharmacies and might have been just the tip of the iceberg). He was not taking all of these medications but was most certainly selling them on the street, presumably one of the biggest suppliers in his town at the time. How many became addicted on a long-term basis because of this one individual? We will never know. We caught him by dumb luck, but with NASPER the pharmacist would have had access to this information and could have stopped this before it began.

CURRENT STATE PROGRAMS

While approximately 15 States (CA, HI, ID, IL, IN, KY, MA, MI, NV, NY, OK, RI, TX, UT, and WA) currently have some form of electronic monitoring program (two more—VA and FL—are pursuing programs), only two allow physicians and/or pharmacists access to this information. Doctors are on the front line of this battle and it is our licenses that are at jeopardy when a patient abuses or diverts their medications. How can we be expected to properly monitor and prevent our patients from becoming addicted to these very powerful medications if our access to this information is restricted? These medications are safe when used properly, but dangerous and potentially lethal when used improperly. Many pain medications including the most abused medication in this country, Hydrocodone, come mixed with acetaminophen (Tylenol). Patients who take excessive amounts of acetaminophen can develop liver and/or kidney disease.

The 15 State programs have a common goal of reducing prescription drug abuse and diversion but vary in their objectives, design, and operation. They do not communicate nor share information with each other on an on-going basis. Only four of the State programs collect information on schedule II, III, and IV controlled substances, one collects data on schedule II and III, and the rest II only. (Schedule II includes morphine, oxycodone-Oxycontin, methadone, etc.; schedule III includes hydrocodone-vicoden, Tylenol with codeine, etc.; and schedule IV includes sedatives such as Valium, Xanax, etc.). Since the most widely abused medication in the U.S. is hydrocodone (this has been shown in multiple studies), it is clear that the majority of State programs inadequately address the whole problem (only 5 of 15 programs collect information on schedule III controlled substances). Most of the State programs were designed and implemented to assist law enforcement in identifying and preventing drug diversion but do not allow the physician or pharmacist to participate in this quest.

KASPER, the Kentucky program which served as the model for NASPER was designed after, is often quoted as the most effective program in the country. Unfortunately, due to the lack of an effective and comprehensive program in neighboring States, this program has not fully achieved what it is capable of. This is due to the highly mobile nature of our society and the ease with which patients can obtain medications in adjacent States. To be truly effective, we need a national program with each State collecting similar data and which allows physician access to the information from all States. I am from Connecticut and within 1 to 2 hours can drive to six other States (PA, NY, NJ, MA, RI, VT, NH). A single State program without exchange of information would not completely address the problem of doctor shopping.

HAROLD ROGERS PRESCRIPTION DRUG MONITORING PROGRAM

The Harold Rogers Prescription Drug Monitoring Program, which began to receive funding in 2002, encouraged, but did not require, each State to institute an electronic monitoring program. It placed no requirements on what information was to be collected (schedule II, III, and/or IV), nor did it encourage physician or pharmacist access to this information. There were no provisions for exchange of information between States, due in part, to the lack of uniformity between programs. As we have learned, those involved in prescription drug abuse and diversion are smart and adaptable. To circumvent this solution these individuals began to cross State lines to obtain additional medications, often selecting adjacent States without an electronic monitoring program. In addition, many States dealing with budget deficits, elected not to start their own programs due to insufficient funding through this program (one of the reasons that Connecticut has no program). While the intentions of this program were good and Congressman Rogers should be commended for this initial effort, we have discovered many deficiencies, which have been addressed and dealt with in NASPER.

DEA'S ROLE IN PRESCRIPTION MEDICATION ABUSE AND DIVERSION

The DEA is able to control diversion at the wholesale level with regulatory, nationwide monitoring databases and investigative activities, but cannot effectively deal with diversion at the retail level. It simply does not and cannot have the necessary manpower to accomplish this effectively. From a privacy standpoint, even if the DEA could accomplish this monumental task, it would be better, and make more sense, for the physician to monitor his/her own patients.

A Massachusetts DEA report in 2004 describes, "well-organized doctor shopping rings, forged and/or altered prescriptions, and diversion from individual prescriptions are the most commonly found diversion methods in the State." NASPER, through physician and pharmacist involvement, would stop these forms of diversion. The DEA's report on Connecticut states that "diverted pharmaceuticals are also prevalently abused in CT . . . the diversion and abuse of prescription opiates such as Oxycontin, Vicoden, and Percocet are increasing rapidly. Diverted pharmaceuticals typically are obtained through common diversion techniques including prescription fraud, improper prescribing practices, "doctor shopping", and pharmacy theft." In Alabama, the DEA report states that "Oxycontin is still the number one drug abused across the State . . . Alabama is a major market for Dilaudid. Distribution in Alabama (of Dilaudid) has increased due to the fact that the price of heroin in the New York area has fallen dramatically causing the bottom to fall out of the market for Dilaudid. Distribution networks have targeted metropolitan areas of Alabama, as the price they receive for Dilaudid in Alabama is higher."

STATE MEDICAID SPENDING

It has been reported that some States have increased drug spending within the Medicaid system by as much as 65 percent in 2003. As you are aware, Medicaid programs provide medications at government expense to those who cannot afford their own healthcare. The State of Connecticut's Medicaid program spent \$11.7 million on 44,500 Oxycontin prescriptions in 2003. The State of Massachusetts' Medicaid system spent over \$20 million in both 2003 and 2004 on Oxycontin (over 80,000 prescriptions each year). In Massachusetts, Oxycontin was the seventh most costly medication in total dollars spent and was the 26th most prescribed medication within the State Medicaid program. Percocet was the fourth most prescribed medication (a less expensive medication, so in total dollars more is spent on Oxycontin). Studies have shown that the incidence of abuse and diversion within the Medicaid systems is 2-3 times that of the general population and approaches 20 percent. In a soon to be published study by Manchikanti et al., patients with only Medicaid coverage showed a 39 percent incidence of illicit drug usage as compared to 17 percent with third party insurance (Medicare patients with/without third party coverage were only 10 percent). Combining the use of illicit drugs and misuse of prescription medications showed the highest incidence in the Medicaid group, 60 percent (versus 24 percent in the Medicare group with/without third party insurance). The money saved directly by limiting drug diversion and abuse in this population will in itself easily pay for the NASPER program. Just as importantly, with NASPER, we will be protecting America from at least one major source of medication that is reaching our streets.

The majority of money spent on substance abuse comes from Federal sources with our national drug control policy on track to spend over \$12 billion in 2005. HHS funds 32 percent of the \$572 billion spent on Medicaid (or \$183 billion) programs. It is estimated that 15 percent of the Medicaid recipients abuse/misuse prescription medications. A 1 percent savings to Medicaid will result in a saving of \$1.83 billion and more realistically this could approach 5 percent or \$9 billion. A comprehensive controlled substance monitoring program will result in significant cost savings from this point of view alone and clearly makes sense. The center on Addiction and Substance Abuse (CASA), in 1995, performed an extensive study of the costs of substance abuse to Federal entitlement programs and found that healthcare and disability costs alone were \$77.6 billion. The Levin group projected the economic costs of drug abuse in 2000 at \$160.7 billion. The proposed 2005 budget from the White House for prescription drug diversion control will increase from \$20 million to \$138 million, with most of the funds directed at reducing the non-medical use of prescription drugs.

BEYOND NASPER

More needs to be done than NASPER, but this will be a great start. The Internet remains a major problem and will need to be addressed. I would urge you to create a task force to deal with this rapidly growing problem. Tens of thousands of people

in this country are becoming addicted to narcotic medications that they obtain through the Internet. I have placed three people into rehabilitation programs who bought their medications over the Internet and subsequently became addicted in this fashion. We must also address the availability of qualified drug rehabilitation programs and ensure insurance coverage for those who have traveled down the wrong pathway. Many of the available beds in our drug rehabilitation programs are now occupied by recovering prescription drug addicts. Preventive medicine, as can be accomplished with NASPER, represents the better solution, especially given the high incidence of recidivism with this disease (estimated between 50–80 percent).

PRIVACY CONCERNS

The most common objection that I have heard in regard to NASPER has to do with privacy issues. We have, however, taken tremendous safeguards to protect patient's privacy. First, this program is fully HIPPA compliant. Patients must sign a release in order for the physician or pharmacist to obtain information. Anyone obtaining information, other than the patient's pharmacist or physician, (or these individuals without appropriate consent), is subject to a fine of \$25,000 per offense. Law enforcement only has access to this information through appropriately obtained subpoenas, showing just cause. I am frequently asked "what about the patient who won't sign the release of information." This will certainly lead to a discussion between the patient and the physician, and of course, will raise suspicions. Some patients may have a justified reason, others will not.

All States, regardless of whether there is a State prescription monitoring program or not, already have the authority under State laws to conduct investigations of the records of individuals alleged to be involved in prescription drug diversion and abuse, including the records of prescribing physicians and dispensing pharmacies.

I have explained NASPER to many of my patients who are taking chronic medications legitimately, and asked if they would object to the government collecting this information. Uniformly they have all said "no", because for them it will help legitimize what they are doing and will take away some of the stigma associated with taking chronic pain medications. They resent being adversely labeled because of those who choose to abuse and misuse this treatment approach. The abuse and diversion of drugs to inappropriate sources, does as much to hurt the treatment of pain in this country, than the under treatment that we so frequently hear about.

THE DECADE OF PAIN CONTROL

The United States Congress has declared the decade of 2001–2010 the "Decade of Pain Control." The use of chronic narcotic pain medications to treat pain is now well accepted by most individuals in this country. Therefore, there should not be a stigma attached to someone who is taking these medications for medically appropriate and indicated reasons. Abuse and diversion undermine the great efforts and advances that we have achieved in this treatment arena. Our ability to limit these factors will only help to foster the appropriate use of medications for the treatment of pain.

Patients will benefit from the NASPER program by improving the treatment of pain through reduced suspicions, increased access, and improved physician comfort in prescribing medications. Patients who are doctor shopping will benefit from earlier physician intervention. This program will help to stabilize and improve the patient-physician relationship. Law enforcement cannot possibly keep up with the increasing number of drug sales, associated criminal activities, DUI's and other related activities. NASPER will help law enforcement do their job more effectively by decreasing the availability of one major source of drugs.

STAND TOGETHER—AMERICA NEEDS NASPER

NASPER is a bipartisan piece of legislation that is good for America and that every legislator should support. In this election year, which has more than enough division and partisanship, we ask both Democrats and Republicans to stand together on the important issue of prescription drug abuse and show this country that both parties are committed to protecting Americans. As an actively practicing pain physician, I understand that it is important to treat pain; this is something I do every day (I perform over 10,000 patient visits per year in my practice), but I also recognize that we must deal with this rapidly growing problem. While there is clearly a role for these medications, they must be controlled and used properly or they can be dangerous. Perhaps the pendulum has swung too far the other way. I believe that narcotic medications are safe and medically appropriate for the treatment of pain, provided that they are prescribed and controlled by a single provider. This is good medicine. That doctor, at his own choosing, can decide what is the right dosage

for a given patient; but when multiple physicians are prescribing simultaneously, this is a prescription for disaster.

CONCLUSION

Senators, I don't care much for politics but I do care about the right cause, and that is what makes sense for the safety of our patients. NASPER will not only improve quality of patient care, but also make America a safer place. We have an obligation to do whatever we can to protect the children of our country (including my 11 and 13 year old) by reducing the supplies of prescription medications on the streets. NASPER makes sense for this country at this time; it will eliminate or at least significantly decrease one of the largest sources of prescription medications being diverted for non-medical purposes. It will help prevent patient substance abuse, decrease the chance of addiction due to better physician medication monitoring, and lower the number of people requiring drug rehabilitation (patients, true addicts, and the misguided who were unlucky enough to get involved in the "Oxy-Craze").

The costs are minimal to start and operate this program. In reality the program will more than pay for itself through decreased expenditures on medications within the Medicaid system and soon to be available Medicare prescription benefit plans. It will also decrease healthcare costs in terms of fewer ER visits, reduced number of rehab program visits (long-term), and other related healthcare expenditures (including cases of HIV). How often does a bill, supporting a new program, actually result in a net savings? Perhaps the most important benefit of H.R. 3015/NASPER, is its positive effects on family life, as opposed to the destructive effects that these medications can have, when taken improperly and for non-medical reasons. How many human lives will NASPER save? Can we afford to continue ignoring this problem?

[Whereupon, at 3:20 p.m., the committee was adjourned.]

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